SUPREME COURT, U. S.

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IN THE

Supreme Court of the United States

OCTOBER TERM 1974

No. 74-1185

FIRESTONE PLASTICS COMPANY, a Division of THE FIRESTONE TIRE & RUBBER COMPANY, UNION CARBIDE CORPORATION, and THE SOCIETY OF THE PLASTICS INDUSTRY, INC.

Petitioners,

v.

UNITED STATES DEPARTMENT OF LABOR, JOHN T. DUNLOP, SECRETARY, U. S. DEPARTMENT OF LABOR, JOHN H. STENDER, ASSISTANT SECRETARY OF LABOR FOR OCCUPATIONAL SAFETY AND HEALTH, AMERICAN FEDERATION OF LABOR AND CONGRESS OF INDUSTRIAL ORGANIZATIONS, and INDUSTRIAL UNION DEPARTMENT, AFL-CIO,

Respondents.

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

March 19, 1975

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TABLE OF CONTENTS

	Page
OPINION BELOW	2
JURISDICTION	2
QUESTIONS PRESENTED	2
CONSTITUTIONAL, STATUTORY AND REGULATORY PROVISIONS INVOLVED	4
STATEMENT OF THE CASE	5
The Act	5
OSHA Proceedings Concerning Vinyl Chloride	6
The Final Standard	7
The Hearing	8
1. Medical testimony	8
2. Technological infeasibility	10
3. Economic infeasibility	11
The Secretary's Principal Findings and Conclusions	11
1. Medical considerations	12
2. Infeasibility of compliance	12
3. Purported justification for the standard	13
The Decision Below	14
REASONS FOR GRANTING THE WRIT	14
1. The Court Below Improperly Refused to Apply the "Substantial Evidence" Test Required by the Statute	15
2. The Court Below Improperly Failed Even to Consider the Extensive Evidence Contrary to the Secretary's Determination	19

Page

3. The Court Below Improperly Interpreted the Statutory Requirement that the Secretary's Standard Must be "Feasible" 21

(a) Technology-forcing 22

(b) Differing compliance capabilities of the VCM and PVC industries 24

(c) Economic feasibility 25

4. The Court Below Improperly Allowed the Secretary to Adopt a Standard Which, Because It Merely Repeats the Statutory Criterion of "Feasibility," Violates the Legislative Requirement That the Standard Must Be Stated in Objective Terms, and Is Also Unconstitutionally Vague 25

CONCLUSION 27

APPENDIX A 1a

APPENDIX B 21a

APPENDIX C 63a

TABLE OF AUTHORITIES

CASES:

Associated Industries of New York State, Inc. v. *Department of Labor*, 487 F.2d 342 (2d Cir. 1973) .. 16, 18

Boutilier v. *Immigration and Naturalization Service*, 387 U. S. 118 (1967) 27

Chrysler Corporation v. *Department of Transportation*, 472 F.2d 659 (6th Cir. 1972) 2, 3, 26

Connally v. *General Construction Co.*, 269 U. S. 385 (1925) 27

Page

Dry Color Manufacturers' Association, Inc. v. *Department of Labor*, 486 F.2d 98 (3d Cir. 1973) 17

Ethyl Corporation v. *EPA* (No. 73-2205, D. C. Cir., January 28, 1975) 20

Federal Trade Commission v. *Colgate-Palmolive Co.*, 380 U. S. 374 (1965) 27

Florida Peach Growers Association, Inc. v. *United States Department of Labor*, 489 F.2d 120 (5th Cir. 1974). 17

Industrial Union Department, AFL-CIO v. *Hodgson*, 499 F.2d 467 (D.C. Cir. 1974) 20, 24, 25

M. Kraus & Bros. v. *United States*, 327 U. S. 614 (1946) 27

Natural Resources Defense Council, Inc. v. *EPA*, 489 F.2d 390 (5th Cir. 1974), *cert. granted sub nom., Train* v. *Natural Resources Defense Council, Inc.*, 42 L.Ed.2d 46 (1974) (No. 73-1742) 23

National Roofing Contractors Association v. *Brennan*, 495 F.2d 1294 (7th Cir. 1974), *cert. denied*, 42 L.Ed.2d 801 (1975) 17

Portland Cement Association v. *Ruckelshaus*, 486 F.2d 375 (D.C. Cir. 1973), *cert. denied*, 417 U.S. 921 (1974) 23, 27

Synthetic Organic Chemical Manufacturers Association v. *Brennan*, 503 F.2d 1155 (3d Cir. 1974), *petition for cert. pending* (No. 74-789, filed December 21, 1974) 17, 18

United States v. *Mersky*, 361 U.S. 431 (1960) 27

Universal Camera Corporation v. *N.L.R.B.*, 340 U.S. 474 (1951) 16, 19

Page

CONSTITUTION AND STATUTES:

Constitution of the United States, Amendment V 4

Automobile Safety Act, 15 U.S.C. § 1381 *et seq* 23

Clean Air Act, 42 U.S.C. § 1857 *et seq* 23

Judicial Code:

28 U.S.C. § 1254(1) 2

Occupational Safety and Health Act, 29 U.S.C. § 651 et seq 5

29 U.S.C. § 651(b) 5

29 U.S.C. § 654(a)(1) 5

29 U.S.C. § 654(a)(2) 5

29 U.S.C. § 655(b)(5) 4, 21, 26

29 U.S.C. § 655(f) 2, 4, 15

REGULATIONS:

29 C.F.R. § 1910.93(a), Table G-1 (1972) 6

29 C.F.R. § 1910.93q:

29 C.F.R. § 1910.93q(c) 7

29 C.F.R. § 1910.93q(f)(2) 8, 26

29 C.F.R. § 1911.15(b)(2) 5

39 Fed. Reg. 12342 7

OTHER AUTHORITIES:

S. Rept. No. 91-1282, 91st Cong., 2d Sess. (1970) 21, 23

116 Cong. Rec. 42206 (1970) 16

116 Cong. Rec. 36512 (1970) 23

116 Cong. Rec. 32901-2 (1970) 23

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Respondents.

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

Petitioners pray that this Court issue a writ of certiorari to review the opinion and judgment of the United States Court of Appeals for the Second Circuit entered in this case on January 31, 1975.

OPINION BELOW

The opinion of the United States Court of Appeals for the Second Circuit is not yet reported. It is set forth in Appendix A hereto, pp. 1a-19a.

JURISDICTION

The Judgment of the Court of Appeals was entered January 31, 1975. A copy is included in Appendix A hereto, at p. 20a. This Court's jurisdiction is invoked pursuant to 28 U.S.C. § 1254(1). The jurisdiction of the Court of Appeals was conferred by 29 U.S.C. § 655(f).

QUESTIONS PRESENTED

1. Whether, despite the requirement of the Occupational Safety and Health Act that the Secretary's regulatory standards issued pursuant to the Act must be "supported by substantial evidence in the record considered as a whole," the reviewing court may refuse to apply this test if the Secretary asserts that his standard is based on "policy judgments" because the factual basis is insufficient; and, regardless of the test applied, whether the court may refuse even to consider the evidence opposed to the standard?

2. Whether, in light of the statutory requirements that regulatory standards must be "feasible" and must insofar as practicable be "expressed in terms of objective criteria," the Secretary may promulgate a standard that he concedes is infeasible; and whether he can cure that deficiency by requiring employers to meet the standard insofar as it is "feasible" for them to do so, without specifying in any manner what actions will constitute compliance?

* * *

Petitioners do not ask this Court to review the evidence of record. Rather, they ask the Court to decide the appropriate standard for judicial review of the Secretary's determination and to decide other important questions of statutory construction and Constitutional law raised by the Secretary's action and its affirmance by the Court of Appeals.

Petitioners do not question the fact that vinyl chloride is a health hazard at very high concentrations. This case does not, however, involve that issue. Rather, it involves the Secretary's prohibition of exposures to vinyl chloride at virtually *any* level, even though he recognizes that the data are inadequate to establish a medical need for such a stringent standard, and even though he further concedes that the standard is not technologically achievable.

The Court below refused to review the validity of the Secretary's action in accordance with the "substantial evidence" test specified by Congress in the Occupational Safety and Health Act. Furthermore, the Court did not consider in any way the extensive evidence of record which shows the Secretary's standard to be unnecessary and infeasible. In both respects, the Court did not adequately exercise its judicial responsibility as required by the statute. It thereby gave the Secretary virtually unrestrained license to adopt standards without sufficient factual basis and without effective judicial review. These are the errors of which Petitioners complain.

Petitioners submit that this case presents issues of exceptional importance. They affect sound judicial practice, the Secretary's future administration of a major federal regulatory program, and the viability of

an important domestic industry. Petitioners therefore ask this Court to grant their petition in order to resolve these questions.

CONSTITUTIONAL, STATUTORY AND REGULATORY PROVISIONS INVOLVED

Constitution of the United States:

Amendment V:

"... nor shall any person ... be deprived of life, liberty, or property, without due process of law...."

Statutes:

29 U.S.C. § 655(b)(5):

"The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired."

29 U.S.C. § 655(f):

"Any person who may be adversely affected by a

> standard issued under this section may . . . file a petition . . . with the United States court of appeals . . . for a judicial review of such standard. . . . The determinations of the Secretary shall be conclusive if supported by substantial evidence in the record considered as a whole."

These and other relevant sections of the Occupational Safety and Health Act are set forth in full as Appendix C, pp. 63a-98a.

Regulations:

29 C.F.R. § 1911.15(b)(2):

> "The presiding officer shall provide an opportunity for cross-examination on crucial issues."

29 C.F.R. § 1910.93q, because of its length, is set forth in full as Appendix B, pp. 21a-62a.

STATEMENT OF THE CASE

The Act

In 1970, Congress enacted the Occupational Safety and Health Act, 29 U.S.C. § 651 *et seq.* The purpose of the Act is "to assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources." 29 U.S.C. § 651(b). The Act requires every employer engaged in interstate commerce to provide his employees a place of employment which is free from "recognized hazards that are causing or are likely to cause death or serious physical harm." 29 U.S.C. § 654(a)(1). The employer must also comply with occupational safety and health standards promulgated by the Secretary of Labor, 29 U.S.C. § 654(a)(2). The Secretary administers the Act through the Occupa-

tional Safety and Health Administration of the Department of Labor (OSHA).

OSHA Proceedings Concerning Vinyl Chloride

Corporate petitioners manufacture polyvinyl chloride (PVC) resins by processing the vinyl chloride monomer (VCM). Petitioner Society of the Plastics Industry includes members who manufacture VCM and PVC and fabricate a large number of consumer and industrial products containing vinyl chloride. J.A. 540.[1] The size and economic importance of the industry are indicated by the fact that domestic productive capacity for PVC alone was 5.4 billion pounds in 1974. J.A. 3469.

The OSHA standard at issue relates solely to exposure levels for VCM, since PVC in itself is not alleged to cause a health problem.

VCM is a gas at normal room temperature and pressure. It has long been known to pose risks of fire, explosion and toxicity at very high concentrations. Accordingly, in 1971 OSHA promulgated a standard limiting employee exposure to VCM to 500 parts per one million parts of air (expressed as 500 ppm).[2]

In January 1974, The B. F. Goodrich Company reported to the National Institute of Occupational Safety and Health ("NIOSH") that four of its long-term employees had died of a rare form of liver cancer known as angiosarcoma.[3] NIOSH relayed this infor-

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[1] References to "J.A. ——" are to the Joint Appendix filed in the Court below.

[2] 39 C.F.R. § 1910.93(a), Table G-1 (1972).

[3] Since the initiation of large-scale PVC production during World War II, the record shows that there have been 13 cases of

mation to OSHA. On February 15, 1974, OSHA held a hearing on the possible hazards of VCM. On April 15, 1974, it promulgated an emergency temporary standard providing that employers must reduce exposures to 50 ppm. 39 Fed. Reg. 12342.

On May 10, 1974, OSHA proposed a new permanent standard to reduce VCM exposure to "no detectable level." 39 Fed. Reg. 16896. Hearings on the proposal commenced June 25 and concluded on July 11.

The Final Standard

On October 1, 1974, the Secretary promulgated the new permanent standard, to be effective January 1, 1975. 39 Fed. Reg. 35890 (October 4, 1974).[4] The maximum permissible level was set at 1 ppm TWA over any eight-hour period, with a ceiling of 5 ppm for any period not exceeding 15 minutes.[5] This criterion is essentially the same as the "no detectable level" standard suggested in the proposed regulations.[6] The standard requires employers immediately to reduce exposures of all employees to the 1 ppm level. 29 C.F.R. § 1910.93q (e), Appendix B, p. 50a. It also provides that if

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angiosarcoma among domestic PVC workers. J.A. 3258. All involve employees exposed to VCM during earlier periods of time when VCM concentrations in PVC plants were far higher than at present. J.A. 3258, 3289-91.

[4] The standard was amended in certain details on December 2, 1974, 39 Fed. Reg. 41848 (December 3, 1974).

[5] TWA ("time weighted average") is the sum of the exposure for any specified period of time divided by that time period.

[6] The change in language reflects the fact that, with presently available monitoring technology, an exposure level of 1 ppm (±50%) is the lowest that can be detected. Because the two standards are essentially identical, the description in the text of the nature of the evidence presented at the hearing applies to the promulgated standard as well as to the proposed standard.

"feasible engineering and work practice controls which can be instituted immediately are not sufficient to reduce exposures . . . [to 1 ppm], they shall nevertheless be used to reduce exposures to the lowest practicable level, and shall be supplemented by respiratory protection. . ." 29 C.F.R. § 1910.93q(f)(2), Appendix B, p. 52a.

The Hearing

1. Medical testimony

The factual data presented at the OSHA hearing did not prove a medical need for a standard in the range selected by the Secretary. On the contrary, a number of medical witnesses testified specifically that exposures at much higher levels have no adverse effect on human health. The Dow Chemical Company presented the only record evidence relating health and mortality experience to specific levels of vinyl chloride exposure. The evidence showed no statistically significant deviation in medical experience for employees exposed to vinyl chloride even at levels as high as 200 ppm. J.A. 1185.

Studies by other researchers showed that malignancies were lower than average for employees exposed to VCM levels below 200 ppm (J.A. 1744); that overall mortality among employees exposed to VCM was only 75% of the statistical expectation for the general population (J.A. 665-706); and that no cases of angiosarcoma were found in a group of more than 1,000 employees exposed to vinyl chloride for approximately the same number of years as, but at lower exposures than, the population that produced the 13 cases of angiosarcoma—although, as a statistical matter, 21 cases should have resulted in the study group if vinyl chloride were actually a cause of angiosarcoma

at the tested levels (50 ppm and above). J.A. 663. These conclusions were confirmed by three additional studies of past and present employees. J.A. 1032, 1309, 2665.

In the face of these substantial medical data, OSHA showed only that VCM is carcinogenic in man at very high levels of exposure—a proposition not contested by any party. J.A. 316. OSHA also produced clinical evidence, as did industry itself, that VCM is carcinogenic in rats and mice at 50 ppm. J.A. 175, 6044. No facts were presented proving that the carcinogenicity of VCM can be extrapolated from rats and mice to humans. Nor were there facts indicating whether VCM is carcinogenic in rats and mice at any level of exposure lower than 50 ppm.

OSHA's only "evidence" allegedly indicating a medical need for the Secretary's standard was conclusory testimony that exposures should be reduced below the detectable level because no level of exposure has been shown to be safe. None of these witnesses (upon whom the Court below so heavily relied) produced any factual support for his view.[7]

On the contrary, the tenor of their testimony is reflected in the following examples. The only witness who based his recommendation on the extrapolation of

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[7] The record also contained the 1970 report by the Surgeon General's Ad-Hoc Committee on the Evaluation of Low Levels of Environmental Chemical Carcinogens, which expresses the view that if a substance causes cancer in two or more animal species this finding may, by extrapolation, indicate a carcinogenic hazard to man at any exposure level. The authors of the report were not subject to cross-examination in the OSHA hearings. The report contains no reference to vinyl chloride. It thus supplies no factual data with respect to the question at issue in the hearing and it provides no factual basis for the Secretary's determination.

test results from rats and mice to man, conceded that his opinion depended upon a philosophical hypothesis postulating an invariable "continuity of nature." J.A. 270. Every other witness rejected the validity of that extrapolation. J.A. 480, 496, 977, 1225, 1275, 1432, 2000, 2991, 3728, 164-168, 2001-2003, 615, 1224-N-1224-O, 1323. One of these other witnesses told OSHA that "there is no way of projecting from the animal data to man." J.A. 3729. This witness recommended the Secretary's standard, yet he frankly admitted that projecting the known effect of exposure to vinyl chloride at high levels "is speculative at best. . . . [The data] give no grounds for extrapolating to the unknown. More fundamentally, there is no proven or theoretical reason for extrapolating the curve." J.A. 3728-29. And he concluded that "a standard cannot be set on the basis of factual medical, toxicologic, epidemiologic, or pharmacologic data. Such data do not exist." J.A. 3735. As this witness said, "The Record contains no reliable information with regard to the quantity of vinyl chloride that is hazardous to man." J.A. 3727.

2. Technological infeasibility

The record makes clear that the Secretary's standard is not technologically feasible. The Secretary himself so concedes. 39 Fed. Reg. 35892-35894, Appendix B, pp. 32a-33a, 38a-39a. All of the factual evidence demonstrates that the engineering controls and work practices necessary to comply with the OSHA standard do not now exist, and that there is no reason to believe they can be developed in the foreseeable future. J.A. 560; 754-763; 938-948; 1096; 1319; 1329-1333; 1692-1693.[8]

[8] Although several witnesses alleged the contrary, none possessed engineering or other relevant expertise and none supported his assertion with facts.

OSHA admitted at the hearing that it possessed no technological or engineering studies supporting the standard. J.A. 1366-1367. Presumably for this reason, the agency announced on the last day of the hearing that it had contracted with a private consulting firm, Foster D. Snell, Inc., to conduct a study of the technological feasibility of the proposed standard and an analysis of its economic impact. OSHA included the Snell report in the record after the close of the hearing and refused to permit cross-examination as required by Section 1911.15(b)(2) of its own regulations.[9] Yet even this report confirms that the OSHA standard is not feasible and would threaten the continued existence of the entire industry. J.A. 3584-3589.

3. Economic infeasibility

The record contains considerable evidence that the proposed standard is not economically feasible. The Snell report, cited above, concludes that if a 1 ppm standard were promulgated, the cost of attempted compliance would be so great that the entire PVC industry in the United States would be "endangered." J.A. 3566, 3587. The record contains no evidence that the standard is economically feasible.

The Secretary's Principal Findings and Conclusions

The Secretary's reasons for the final standard appear in his introduction to the regulations:

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[9] OSHA also refused to permit cross-examination of two medical doctors whose reports it placed in the record after the hearing closed and upon which it evidently relied in setting the standard. The agency's failure to comply with its own regulations was challenged in, but not considered by, the Court below. The issue is encompassed within the questions presented in this petition.

1. Medical considerations

The Secretary recognizes that there is insufficient factual evidence that his standard is necessary to protect employees' health. 39 Fed. Reg. 35891-35892, Appendix B, pp. 27a-33a. He nonetheless assumes that, since vinyl chloride induces cancer in man at very high exposure levels and in rats and mice at 50 ppm, no safe level exists. He asserts that, in order to set a specific exposure level, OSHA need not prove that the level is required to assure health and safety:

> "In our view, the demonstration of cancer induction in humans at a particular level is not a prerequisite to a determination that a substance represents a cancer hazard at that level." 39 Fed. Reg. 35892, Appendix B, pp. 31a-32a.

2. Infeasibility of compliance

The Secretary also concedes that industry cannot comply with the 1 ppm standard when it becomes effective:

> "We agree that the PVC and VC establishments will not be able to attain a 1 ppm TWA level for all job classifications in the near future. We do believe, however, that they will, in time, be able to attain levels of 1 ppm TWA for most job classifications most of the time." 39 Fed. Reg. 35892, Appendix B, p. 33a.
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> * * *
>
> "We recognize that many employers covered by the standard can not currently achieve compliance with the permissible exposure limit solely by the use of feasible engineering and work practice controls." 39 Fed. Reg. 35893, Appendix B, p. 38a.
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> * * *
>
> ". . . [W]e are presently unable to determine when it will be feasible for most establishments to reduce

exposure levels to the permissible level." 39 Fed. Reg. 358944, Appendix B, p. 39a.

The Secretary acknowledges that the "record also reflects broad generic distinctions between the compliance capabilities of the VC and PVC industries." 39 Fed. Reg. 35893, Appendix B, p. 38a. He nonetheless makes no allowance for these differences, but applies the standard identically to both industries.

The Secretary does not discuss the question of economic feasibility.

3. Purported justification for the standard

In light of these concessions, the Secretary asserts that, where the record affords insufficient factual support, he is nonetheless permitted to adopt regulations on the theory that they are justified as "policy judgments":

> "Where decisions can be based on record evidence, this has been done. Where, however, factual certainties are lacking or where the facts alone do not provide an answer, policy judgments have been made." 39 Fed. Reg. 35892, Appendix B, p. 33a.

On the basis of this rationale, the Secretary concludes:

> ". . . the precise level of exposure which poses a hazard and the question of whether a 'safe' exposure level exists, cannot be definitely answered on the record. Nor is it clear to what extent exposures can be feasibly reduced. We cannot wait until indisputable answers to these questions are available, because lives of employees are at stake. Therefore, we have had to exercise our best judgment on the basis of the best available evidence." 39 Fed. Reg. 35892, Appendix B, p. 33a.

The Decision Below

On October 1, 1974, Petitioners Union Carbide and Society of the Plastics Industry filed timely petitions for review of the Secretary's action in the United States Court of Appeals for the Second Circuit.[10] After oral argument, the Court stayed the effectiveness of the regulations pending its decision on the merits. On January 31, 1975, the Court entered its opinion denying the petitions.

REASONS FOR GRANTING THE WRIT

The decision below makes inoperative crucial provisions of the Occupational Safety and Health Act. It gives the Secretary virtually unrestrained license to promulgate standards that concededly do not comply with the statutory requirements, and to do so without meaningful judicial review. It thus presents important questions of Federal law which should be decided by this Court. Their significance is emphasized by the fact that, in numerous respects, the decision below conflicts with the decisions of other Circuits.

The Occupational Safety and Health Act is a major Federal regulatory statute which has been in effect since 1970. It reaches every employer and worker engaged in interstate commerce. It directs OSHA to balance what is optimal against what is practicable. OSHA's role is to assure worker health and safety, but the Act requires the Secretary to temper his regulations with considerations of technological reality and eco-

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[10] Petitioner Firestone filed a motion to intervene in the Second Circuit on the same day. On October 7, 1974, it filed a Petition for Review in the Sixth Circuit. Firestone's subsequent Motion to Transfer that Petition to the Second Circuit was granted on November 15, 1974.

nomic possibility. Hence the standards must be "feasible" and must be based on "substantial evidence in the record considered as a whole."

In this instance, the Secretary has violated these statutory safeguards. With an admittedly inadequate evidentiary basis, he has directed employers to pursue standards which are admittedly infeasible. By allowing him to do so, the Court below has vitiated the process of judicial review specified by Congress.

These issues are central to the proper administration of the Act. Other Circuits have approached the issues differently and have reached contrary results. The inconsistencies produced by the decision below will continue until this Court provides definitive guidance.

To date, this Court has not reviewed the Act at all. The decision below demonstrates the need for the Court now to do so. The questions here presented are of great legal and practical importance. The Court should rationalize the administration of the Act, by both the courts and the Secretary, by resolving the issues on their merits.

1. The Court Below Improperly Refused to Apply the "Substantial Evidence" Test Required by the Statute.

29 U.S.C. § 655(f) provides that, upon judicial review, "The determination of the Secretary shall be conclusive if supported by substantial evidence in the record considered as a whole."[11] The Court below held

[11] The legislative history of the statute demonstrates that Congress meant precisely what it said when it provided that the determinations of the Secretary must be "'supported by substantial evidence in the record considered as a whole.''

As Congressman Steiger of Wisconsin, chief sponsor of the statute in the House, said in discussing the bill as reported out of conference:

that this test was "almost impossible" to apply—and therefore did not apply it—because the Secretary's determination was "essentially legislative" in character. Appendix A, p. 5a. Although the Court professed to follow *Universal Camera Corp.* v. *N.L.R.B.*, 340 U. S. 474 (1951), it did not do so. Instead, it chose a different and lesser test which it did not articulate, except to state that the courts will only inquire whether the Secretary has acted in a "manner calculated to negate the dangers of arbitrariness and irrationality." Appendix A, p. 5a.

The Court thus carved out of the statute a major exception: the substantial evidence test is not applicable whenever the agency's standard under review is based on a "legislative" or "policy" determination. The approach entails the obvious hazard that, as the Secretary finds less evidence to support the action he desires to take, he will increasingly assert that his decision is a matter of "policy" and hence immune to meaningful judicial review. Such a result is precisely contrary to the intent of Congress as expressed in clear statutory language. The decision of the Court below approaches an abdication of judicial responsibility.

The case thus poses a critical question as to the role of the Courts in reviewing determinations under the Act. Its importance is confirmed by the instances in

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"The Secretary's standard will only be sustained by the court if it is supported by 'substantial evidence in the record considered as a whole.' . . . [T]he court review based upon substantial evidence provides a sufficient element of fairness to satisfy me that [the] conference report should be accepted." 116 Cong. Rec. 42206 (1970).

Judge Friendly has explained in *Associated Industries of New York State, Inc.* v. *Department of Labor*, 487 F.2d 342 (2d Cir. 1973), that the substantial evidence test was incorporated in the statute as an explicit compromise between differing procedural provisions in the House and Senate bills.

which the Circuit Courts have already confronted the question during the period that the Act has been in effect. In four such cases, other decisions of the Circuits directly conflict with the decision below.

In *Florida Peach Growers Association, Inc.* v. *United States Department of Labor*, 489 F. 2d 120 (5th Cir. 1974), the Fifth Circuit explicitly rejected the argument that the question on review of an OSHA standard is whether it is arbitrary and capricious, rather than the more searching substantial evidence test. Even though the Fifth Circuit concluded (as the Second Circuit did here) that OSHA's task was "essentially legislative," it held that the substantial evidence test does apply. Moreover—as discussed in the next section of this Petition—the court reviewed and considered the opposing evidence, as the Court below declined to do. In both respects, the decisions directly conflict.

Similarly, in *Dry Color Manufacturers' Association, Inc.* v. *Department of Labor*, 486 F. 2d 98 (3d Cir. 1973), the Third Circuit explicitly ruled that the substantial evidence test is not limited to factual determinations, but applies to all decisions by OSHA.[12]

The decision below also conflicts with the decision of the Seventh Circuit in *National Roofing Contractors Association* v. *Brennan*, 495 F. 2d 1284 (7th Cir. 1974), *cert. denied*, 42 L. Ed. 2d 801 (1975). Once again the

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[12] The view of the Third Circuit as to the proper standard of review is clouded by the fact that a different panel of that court subsequently held in related litigation that the substantial evidence test does not apply to any of the Secretary's determinations except as to factual matters, *Synthetic Organic Chemical Manufacturers Association* v. *Brennan*, 503 F.2d 1155 (3d Cir. 1974). The latter opinion is the subject of a petition for certiorari now pending in this Court (No. 74-789, filed December 21, 1974).

court held that the substantial evidence test applies to all of the Secretary's regulatory determinations under OSHA and reviewed the evidence opposing the standard as well as that supporting it.

Finally, the opinion of the Court below is in conflict with another decision of the Second Circuit itself. In *Associated Industries of New York State* v. *United States Department of Labor,* 487 F. 2d 342 (2d Cir. 1973), the Second Circuit, per Friendly, J., explicitly rejected OSHA's contention that the substantial evidence test does not apply to questions of policy. Having held that the substantial evidence test does apply, the Court examined all of the evidence and invalidated OSHA's action.[13]

The conflicts among the Circuits, the conflicts within the Third and Second Circuits, and the pendency of another petition for certiorari raising the identical issue as to the proper standard of review,[14] all attest to the importance of the question now presented to this Court.

Petitioners also point out that, even if this Court were to conclude that the Fifth and Seventh Circuits—as well as the Second Circuit itself in *Associated Indus-*

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[13] In the usual case, a petition for rehearing en banc would be the appropriate mechanism for resolving such a conflict within a Circuit. This case presents an unusual circumstance, however, which renders that remedy unavailable. No member of the panel which decided this case sits on the Second Circuit bench. The case was heard by a retired Justice of this Court, a retired District Judge, and an active District Judge. Petitioners are informed that this panel was selected because every member of the Second Circuit recused himself. In those circumstances, a petition for rehearing en banc would be futile.

[14] *Synthetic Organic Chemical Manufacturers Association* v. *Brennan,* note 12, *supra.*

tries and the Third Circuit in *Dry Color Manufacturers*—are in error, and that the Act permits the courts to create an exception to the substantial evidence test in the case of "policy" or "legislative" decisions, it would still be necessary to clarify the criteria for determining which decisions are which. The Secretary and the Court below evidently believe that every instance in which the factual record is insufficient gives rise to such a "policy" judgment. Only this Court can provide the requisite guidance.

2. The Court Below Improperly Failed Even to Consider the Extensive Evidence Contrary to the Secretary's Determination.

The decision below also presents the separate question whether, irrespective of the proper standard for judical review, the courts may uphold the Secretary's action without examining the contrary evidence in the record. Here the Court below did not consider or even mention the extensive evidence opposed to the standard. In effect, the Court held that, because human health is involved at high levels of exposure, OSHA may set any standard it pleases even where the factual basis for doing so is deficient or non-existent.

The Court's approach directly contravenes the mandate of *Universal Camera Corp.* v. *N.L.R.B., supra.* That decision requires a reviewing court to determine whether the evidence relied upon by the agency is rendered insubstantial by contrary evidence or evidence from which contrary inferences can be drawn. As Mr. Justice Frankfurter held: "The substantiality of the evidence must take into account whatever in the record fairly detracts from its weight," 340 U. S. at 488. Although the Court below cites and professes to follow *Universal Camera*, it did not make the evidentiary inquiry which that decision requires.

Once again, conflicting decisions in other Circuits highlight the significance of the question. The cases cited in the preceding section of this petition, which hold that the substantial evidence test applies to OSHA standards, also recognize the courts' obligation to weigh the evidence for and against the Secretary's standard. *Industrial Union Department, AFL-CIO* v. *Hodgson,* 499 F. 2d 467 (D.C. Cir. 1974), is to the same effect. There the District of Columbia Circuit conducted a careful review of the evidence, including the evidence opposed to the standard set by the Secretary. The court thus recognized that, whatever standard of review applies, it must examine all of the evidence rather than looking merely to that which tends to support OSHA's action. The Court below did the opposite.

The same conflict exists with *Ethyl Corporation* v. *EPA* (No. 73-2205, D.C. Cir., January 28, 1975), involving EPA's authority to regulate fuel additives under the Clean Air Act. EPA relied specifically on *Industrial Union Department, AFL-CIO* v. *Hodgson, supra,* to argue that where the issue lies "on the frontiers of scientific knowledge" the agency may act as a matter of policy even though the facts are deficient. EPA's argument in *Ethyl* was thus identical to the view of the Court below. Yet the District of Columbia Circuit rejected EPA's approach. The court held that the "*causal connection* between the lead emissions and the harm must be established by relevant scientific and medical evidence." (Slip Opinion, p. 12, emphasis in original.) It weighed the evidence on both sides and invalidated the agency's action. The decisions cannot be reconciled.

3. The Court Below Improperly Interpreted the Statutory Requirement that the Secretary's Standard Must be "Feasible."

29 U.S.C. § 655(b)(5) contains two provisions requiring that the standards promulgated by the Secretary must be "feasible":

> "The Secretary . . . shall set the standard which most adequately assures, *to the extent feasible*, on the basis of the best available evidence, that no employee will suffer material impairment of health . . ." Appendix C, p. 70a (emphasis supplied)
>
> "In addition to the attainment of the highest degree of health and safety protection, other considerations [in promulgating regulatory standards] shall be the latest available scientific data in the field, *the feasibility of the standards*, and experience gained under this and other health and safety laws." *Id.* (emphasis supplied)

The legislative history confirms that Congress intended the Secretary's standards to be feasible.[15]

Despite the clear statutory directive, the Secretary candidly acknowledges that his VCM standard is not feasible. 39 Fed. Reg. 35892-35894, Appendix B, pp. 32a-33a, 38a-39a. Important questions are raised by his admission:

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[15] As explained by Senator Javits, the author of the amendment from which these statutory provisions were derived:

> "As a result of this amendment, the Secretary, in setting standards, is expressly required to consider feasibility of proposed standards. This is an improvement over the Daniels bill, which might be interpreted to require absolute health and safety in all cases, regardless of feasibility, and the Administration bill, which contains no criteria for standards at all." S. Rep. No. 91-1282, 91st Cong., 2d Sess., at 58 (1970).

(a) Technology-forcing

The Court below upheld the Secretary's standard, despite its admitted infeasibility, by holding that the Secretary may adopt standards "which require improvements in existing technologies or which require the development of new technology" and by assuming (without evidence) that the necessary technology would eventually be developed. Appendix A, pp. 16a-17a. This holding presents a series of questions. Is such a "technology-forcing" approach valid in the face of the statutory language which seems explicitly to require the contrary result? Can the feasibility requirement be satisfied simply by assuming that the standard will become feasible at an unspecified future time? Even if OSHA can act on the assumption that the technology will eventually become available, when its advent is not foreseeable, does not the statutory requirement of feasibility at least require deferring the effective date of the regulations until the technology can reasonably be expected to have been developed?[16]

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[16] The Court below relied on its belief that employees can use respirators until compliance becomes possible. The Court overlooked the fact that the respirator provisions do not relieve employers of the continuing obligation to achieve the 1 ppm standard.

In addition, the Court was factually incorrect. While it acknowledged that the self-contained and airhose respirators are "infeasible for full-time use, as well as potentially hazardous," it assumed that the use of other types of respirators is feasible. In doing so, it ignored the evidence demonstrating that full-time use of *any* respirator is infeasible in the VCM and PVC industries. It also erroneously concluded that full-time use would not be required. The record shows, however, that full-time use of respirators would be required for most jobs, including those in offices and cafeterias, as well as for workers using washrooms, if a 1 ppm standard were imposed. J.A. 535-E; 564-566; 722-722-B; 724; 745; 1332; 1948; 2288-2289.

To support its technology-forcing approach, the Court below relied on *Chrysler Corporation* v. *Department of Transportation*, 472 F. 2d 659, 671-672 (6th Cir. 1972), and *Natural Resources Defense Council, Inc.* v. *EPA*, 489 F.2d 390, 411-412 (5th Cir. 1974), *cert. granted sub nom. Train* v. *Natural Resources Defense Council, Inc.*, 42 L. Ed. 2d 46 (1974) (No. 73-1742). Neither decision is apposite. The statutes involved in those cases (the Automobile Safety Act, 15 U.S.C. § 1381 *et seq.*, and the Clean Air Act, 42 U.S.C. § 1857 *et seq.*) both contain technology-forcing purposes which are absent here. The legislative histories make this clear. In adopting the Clean Air Act and the Automobile Safety Act Congress expressly rejected "feasibility" provisions virtually identical to that contained in 29 U.S.C. § 655(b)(5). See *Chrysler Corporation* v. *Department of Transportation, supra; Natural Resources Defense Council, Inc.* v. *EPA, supra; Portland Cement Association* v. *Ruckelshaus*, 486 F. 2d 375, 391 (D.C. Cir. 1973), *cert. denied*, 417 U. S. 921 (1974). See also, comments of Senator Muskie, Senate sponsor of the Clean Air Act Amendments, 116 Cong. Rec. 32901-2 (1970).[17] The Court's reliance on these decisions is therefore misplaced.

In addition, the holding of the Court below, permitting the Secretary to impose a standard that requires the use of unavailable technology, conflicts with a recent holding on this point by the District of Columbia Circuit:

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[17] Such comments contrast sharply with comments by Senators Javits, note 15, *supra*, and Saxbe, 116 Cong. Rec. 36512 (1970), regarding the feasibility requirement of 29 U.S.C. § 655(b)(5).

> "Congress does not appear to have intended to protect employees by putting their employers out of business—either by requiring protective devices unavailable under *existing* technology or by making financial viability generally impossible."

Industrial Union Department, AFL-CIO v. *Hodgson, supra,* at 478 (emphasis supplied).

(b) Differing compliance capabilities of the VCM and PVC industries

The Secretary's standard applies identically to fabricators of vinyl chloride products, manufacturers of vinyl chloride and manufacturers who convert the vinyl chloride monomer into polyvinyl chloride. Yet the record demonstrates that, because of differences in the manufacturing processes involved, it is far more difficult for PVC producers to limit VCM exposure than it is for VCM producers to do so. The Secretary himself concedes that the record "reflects broad generic distinctions between the compliance capabilities of the VC and PVC industries." 39 Fed. Reg. 35893, Appendix B, p. 38a.

Petitioners believe, and argued below, that the Secretary acted improperly by failing to adjust his compliance standards to accommodate these acknowledged differences. The Court below did not consider the point. Yet such an indiscriminate approach, sanctioned by the Court, appears to be a further violation of the statutory requirement that the standard must be feasible, and also to raise a significant Constitutional question.

Once again, the position of the Court below conflicts with *Industrial Union Department, AFL-CIO* v. *Hodgson, supra.* There, as here, the record revealed

that some industries could implement the Secretary's standard more readily than others. Nevertheless, OSHA issued a single standard to be effective for all industries on the same date. For this deficiency the District of Columbia Circuit remanded.

(c) Economic feasibility

The record contains ample evidence that compliance with the Secretary's standard would be economically impossible. It contains no evidence that the standard is economically feasible. Neither OSHA nor the Court below examined the question. Yet, as its legislative history makes clear, the statutory requirement that the Secretary's standard be feasible includes economic feasibility.[18] The District of Columbia Circuit has specifically so held in *Industrial Union Department, AFL-CIO* v. *Hodgson, supra,* at 477-478. Hence the decision below presents the question whether the Federal courts may permit the Secretary to ignore this statutory consideration also. Once again a conflict between the Circuits emphasizes the significance of the question.

4. The Court Below Improperly Allowed the Secretary to Adopt a Standard Which, Because It Merely Repeats the Statutory Criterion of "Feasibility," Violates the Legislative Requirement That the Standard Must Be Stated in Objective Terms, and Is Also Unconstitutionally Vague.

Recognizing that achievement of the one ppm level is not feasible, the Secretary also requires industry to employ "feasible" engineering methods and work practices to reduce exposure to the lowest "practicable"

[18] See, *e.g.*, remarks of Senator Saxbe, note 17, *supra.*

level, 29 C.F.R. § 1910.93q(f)(2), Appendix B, p. 52a.[19] This standard, of course, merely restates the statutory requirement of "feasibility." It contains no guidance, either for industry or for the OSHA regulators themselves, as to what is "feasible" or "practicable." In fact, OSHA's own explanation of its regulations makes clear that it drafted the standard as it did precisely because it could not determine, even after a full hearing, what level of exposure is feasible.

In these circumstances, Petitioners argued in the Court below that the standard is impermissibly vague under the Fifth Amendment to the Constitution and that it also violates the statutory requirement that "wherever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired," 29 U.S.C. § 655(b)(5). As in the case of various others of Petitioners' arguments, the Court below did not discuss the point.

Petitioners submit that the issue is important and should be addressed by this Court. The Secretary's standard is clearly contrary to the statutory language and purpose. The decision of the Court below upholding the standard conflicts, furthermore, with two recent decisions in other Circuits, both of which invalidated agency action for failure to formulate regulations in objective and ascertainable terms, *Chrysler Corporation* v. *Department of Transportation, supra,* at 678,

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[19] As noted above, the Secretary's regulations nonetheless retain the one ppm standard as an unconditional objective. The provisions relating to "feasibility" supplement, but do not alter, the obligation to pursue this objective. Industry remains obligated to work toward an admittedly infeasible goal. The same is true of the respirator provisions of the regulations, which do not affect the employers' obligation to strive to limit exposures to one ppm.

and *Portland Cement Association* v. *Ruckelshaus*, *supra*, at 400-401.[20]

CONCLUSION

The decision below raises important questions of Federal law, relating to the implementation of a major Federal regulatory program and the standards which should govern agency decision-making. The statute involved has already generated considerable litigation and conflicting decisions by the Courts of Appeals. These are matters which have not yet been before this Court, and as to which the Court should now provide guidance.

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[20] The Secretary's standard also violates the Constitutional requirement, which this Court has clearly articulated, that Federal administrative prescriptions may not be vague—particularly where, as here, a failure to comply can invoke criminal sanctions. As this Court has stated:

> ". . . an order's prohibitions 'should be clear and precise in order that they may be understood by those against whom they are directed,' . . . and . . . '[t]he severity of possible penalties prescribed . . . for violations of orders which have become final underlines the necessity for fashioning orders which are, at the outset, sufficiently clear and precise to avoid raising serious questions as to their meaning and application.' "

Federal Trade Commission v. *Colgate-Palmolive Co.*, 380 U.S. 374, 392 (1965) (footnotes omitted). See also, *M. Kraus & Bros.* v. *United States*, 327 U.S. 614, 621 (1946); *Connally* v. *General Construction Co.*, 269 U.S. 385 (1925); and *United States* v. *Mersky*, 361 U.S. 431 (1960). In the last case this Court emphasized that "businessmen must not be left to guess the meaning of regulations." *Id.* at 441.

Moreover, as Mr. Justice Clark himself recognized when he was sitting on this Court, the same principle applies even when criminal sanctions are not involved: ". . . this Court has held the 'void for vagueness' doctrine applicable to civil as well as criminal actions." *Boutilier* v. *Immigration and Naturalization Service*, 387 U.S. 118, 123 (1967).

For these reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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March 19, 1975

APPENDIX

APPENDIX A

Opinion Subject To Be Reviewed

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

Nos. 505, 603-608, 670, 671

Argued December 13, 1974

September Term, 1974

Decided January 31, 1975

Docket Nos. 74-2284, 74-2286, 74-2308, 74-2345, 74-2449, 74-2450, 74-2491, 74-2585, 74-2609

THE SOCIETY OF THE PLASTICS INDUSTRY, INC., *Petitioner*

v.

OCCUPATIONAL SAFETY & HEALTH ADMINISTRATION, ET AL., *Respondents*

HOOKER CHEMICALS & PLASTICS CORPORATION,

and

AIR PRODUCTS AND CHEMICALS, INC.,

and

TENNECO CHEMICALS, INC., *Petitioners*

v.

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, ET AL., *Respondents*

UNION CARBIDE CORPORATION, *Petitioner*

v.

UNITED STATES DEPARTMENT OF LABOR, ET AL., *Respondents*

THE B. F. GOODRICH COMPANY, *Petitioner*

v.

PETER J. BRENNAN, ET AL., *Respondents*

FIRESTONE PLASTICS COMPANY, A Division of the FIRESTONE TIRE & RUBBER COMPANY, *Petitioner-Intervenor*

v.

UNITED STATES DEPARTMENT OF LABOR, ET AL., *Respondents*

UNIROYAL INC., *Petitioner*

v.

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, ET AL., *Respondents*

GENERAL DYNAMIC CHEMICAL CO., INC., *Petitioner*

v.

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, ET AL., *Respondents*

THE DIAMOND SHAMROCK CHEMICAL CO., INC., *Petitioner*

v.

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, ET AL., *Respondents*

An amicus curiae brief was filed on behalf of Chemical Fabrics & Film Association

Before: CLARK, Associate Justice,* BRYAN, District Judge,** and DUFFY, District Judge.***

Petitions for Review of the Vinyl Chloride Regulation, 29 C.F.R. § 1910.93q, of Occupational Safety and Health Stand-

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* United States Supreme Court, Retired, sitting by designation.

** United States District Court, Southern District of New York, Retired, sitting by designation.

*** United States District Court, Southern District of New York, sitting by designation.

ards for the Vinyl Chloride Industry, promulgated by the Secretary of Labor, pursuant to 29 U.S.C. § 655. Petitions are denied.

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MR. JUSTICE CLARK:

This is a petition for review of the health and safety regulations for the vinyl chloride industry, 29 C.F.R. § 1910.93q, promulgated by the Secretary of Labor on October 4, 1974, pursuant to the Occupational Safety and

Health Act, 29 U.S.C. § 651 et seq. (hereinafter OSHA). The standard and the Secretary's statement of reasons for its imposition are set forth at 39 Fed. Reg. 35890-35898. In brief, the Secretary has adopted a standard which requires that no worker is to be exposed to concentrations of vinyl chloride in excess of one part per million (ppm) averaged over any eight-hour period. 29 C.F.R. § 1910.93q (c)(1).

Petitioners—manufacturers of vinyl chloride and vinyl chloride products—make five principal claims: (1) the available scientific and medical evidence does not establish that the 1 ppm exposure level adopted by the Secretary is required by health or safety considerations; (2) that the Secretary violated the requirements of 29 U.S.C. § 655 (b)(5) by adopting a standard which is technologically and economically infeasible for the industry to meet; (3) that the standard is so vague and uncertain in its terms that enforcement will violate the requirements of due process; (4) that there was no substantial evidence in the record to support the Secretary's conclusion that those who fabricate products out of vinyl chloride should be subject to the same requirements as those who produce vinyl chloride; and (5) that the Secretary's sign and labelling requirements unduly and hence unlawfully emphasized the carcinogenic properties of vinyl chloride. We find these contentions meritless, and the petitions for review are accordingly denied.

I.

Scope of Judicial Review

Before proceeding to an examination of the regulations at issue in this case, it would be wise to reemphasize the unique nature of the court's role under OSHA. Although the statute sets forth general policy objectives and a procedural framework, the formulations of specific safety and health policies is left to the Secretary, subject to review in

the United States Court of Appeals. Our mandate is contained in 29 U.S.C. § 655 (f), which states in relevant part:

> The determinations of the Secretary shall be conclusive if supported by substantial evidence in the record considered as a whole.

Yet the traditional "substantial evidence" test is almost impossible of application where, as here, the Secretary's decision-making is essentially legislative in character.

The problems involved in according judicial review in such circumstances have been wisely discussed by Judge McGowan in *Industrial Union Department, AFL-CIO* v. *Hodgson*, 499 F.2d 467 (D.C. Cir. 1974), who pointed out that, under OSHA:

> [T]here are areas where explicit factual findings are not possible, and the act of decision is essentially a prediction based upon pure legislative judgment, as when a Congressman decides to vote for or against a particular bill.
>
> * * * *
>
> [P]olicy choices of this sort are not susceptible to the same type of verification or refutation by reference to the record as are some factual questions. Consequently, the court's approach must necessarily be different no matter how the standards of review are labeled. [499 F.2d at 474-75.]

In these circumstances, Judge McGowan concluded, the reviewing court must recognize that its task defies generalized description and go from there to achieve its paramount objective which "is to see whether the agency, given an essentially legislative task to perform, has carried it out in a manner calculated to negate the dangers of arbitrariness and irrationality in the formulation of rules for general application in the future." *Automotive Parts & Accessories Assn.* v. *Boyd*, 407 F.2d 330, 338 (D.C. Cir. 1968).

Thus armed with these salutary remarks on our limitations and our obligations, we turn to the challenged regulations. The examination of the 4,000-page record in this case has been a prodigious task, aggravated by duplications of testimony, irrelevant exhibits and letters, almost illegible reproduction of documents, and a generally blunderbuss approach in petitioners' briefs. Given the task, however, we have performed it and conclude that the standard laid down by the Secretary is fully supported by the record and well within the requirements of *Universal Camera Corp.* v. *NLRB*, 340 U.S. 474 (1951), and *Assoc. Industries of New York State, Inc.* v. *Department of Labor*, 487 F.2d 342 (2d Cir. 1973), as well as *Industrial Union Department, AFL-CIO* v. *Hodgson, supra.*

II.

Background

There are three basic components of the vinyl chloride industry. First, there are the manufacturers of vinyl chloride itself. A gas at ambient temperatures and pressure, vinyl chloride monomer (VCM) is primarily synthesized by the oxychlorination of ethylene in a handful of large outdoor production plants which resemble oil refineries. Shell, Dow, and Goodrich are the leading producers, accounting for some 50% of the 5.2 billion pounds annually available in the United States. Because of the high degree of automation involved in this manufacturing process, only some 1,500 workers are employed in VCM production. VCM plants are open-air facilities, primarily in the South.

Second, there are the manufacturers of polyvinyl chloride (PVC). Virtually all vinyl chloride is polymerized into thermoplastic PVC resin which serves as the basis for a wide variety of useful plastic products. Goodrich is by far the largest single producer, producing some 20%

of the country's 5.4 billion pounds annually, though in total there are only 21 companies operating the 37 PVC plants. Historically, PVC production has been a "batch" or non-continuous operation carried out in relatively small (2,000-6,000 gallon) "reactors" which require frequent cleaning; the trend, however, is towards substantially larger reactors. PVC plants are not open-air facilities and are generally located in colder climates than VCM plants. They employ some 5,000 workers.

Third, and finally, there are the fabricators of products which utilize PVC resins. Innumerable firms throughout the country, employing thousands of workers, compound PVC with plasticizers, heat stabilizers, lubricants, light stabilizers, flame retardants, or impact modifiers to produce an astounding variety of wares, such as pipes and conduits for building and construction, flooring, wire and cable, furniture, phonograph records, and packaging. In fabrication, residual VCM that has been entrapped in the PVC resin escapes during the heating process, and in this way workers in the fabricating industry are also exposed to vinyl chloride.

It is now clear that the workers in all components of the vinyl chloride industry are subjected to a serious health risk from VCM. Although conclusive proof of the carcinogenic and, in turn, fatal character of VCM did not emerge until early in 1974 when the deaths of three workers in Goodrich's PVC plant at Louisville were reported, strong warning signals had appeared long before. As early as 1949, when the vinyl chloride industry had barely reached its tenth anniversary, a study conducted among vinyl chloride workers in the Soviet Union found liver damage in 15 of 48 workers studied, and in 1958 and 1959, Dow Chemical scientists elicited liver irregularities in rats and rabbits at a 100 ppm concentration of VCM. Although Dow recommended a 50 ppm allowable level in

1961, the industry adhered to its previous 500 ppm standard.

We need not outline in detail the morbid "Vinyl Chloride Chronology", published by an industry spokesman, the Manufacturing Chemists Association (MCA), in a 1974 press release (Joint Appendix at 134-145) in order to illustrate the mounting evidence of VCM's carcinogenicity. Indeed, the record shows what can only be described as a course of continued procrastination on the part of the industry to protect the lives of its employees. In 1967, when the industry had not reached its thirtieth anniversary, upon receiving recurring reports of the softening of the finger tips and bone of VCM/PVC workers, the Manufacturing Chemists Association had the University of Michigan study the causes of this abnormality. Three years later, in 1970, when it was advised that research could not *pinpoint* the cause of the malady *but* recommended a VCM/PVC ceiling of 50 ppm VCM, nothing was done. And in March of the same year, Dr. P. L. Viola of the Regina Elena Institute for Cancer Research in Rome, Italy, published a report that 30,000 ppm VCM exposure for four hours per day, five days per week for a year caused cancer of the skin, lung, and bones of rats, and a few months later at the Tenth International Cancer Congress, described observations of malignant tumors in the ear canals of rats subjected to the same exposure. Apparently relying on Dr. Viola's comment at the close of his abstract that: "No implications to human pathology can be extrapolated from the experimental model reported in the paper," the industry did nothing.

In 1971, MCA began to inquire by letter regarding the conduct of toxicological studies on laboratory animals with VCM and in May of 1971 heard a detailed presentation by Dr. Viola regarding his earlier studies as well as other studies then unreported. The industry began talking about raising funds for epidemiological research on

VCM carcinogenicity, but not until March 30, 1972, did 17 U.S. companies agree to finance such a study. By then, the first deaths of U.S. workers due to VCM exposure were being recorded.

Months were consumed in 1972 by negotiations among the participating company representatives, and it was not until February of 1973 that a protocol was agreed upon and a research contract for animal exposure studies signed. Meanwhile, startling results from European experiments were filtering back to the industry. By January of 1973 it was discovered that European experiments with rats had not only found tumors of the ear canal (which Dr. Viola had reported as early as 1970), but also of the kidneys and liver at concentrations as low as 250 ppm VCM, but not at 50 ppm. This discovery, however, was kept confidential, and it was not even revealed to the National Institute of Occupational Safety and Health (NIOSH) until July 17, 1973.

Earlier, on September 27, 1971, a patient of Dr. J. L. Creech, Jr., plant physician of the B. F. Goodrich Chemical Company in Louisville, Kentucky, died. The patient had been employed for 15 years as a helper and operator in Goodrich's Louisville PVC plant. When first hospitalized, a tentative diagnosis was made of a bleeding duodenal ulcer, but upon re-admittance and after an exploratory laparotomy and biopsy was carried out, he was found to have angiosarcoma of the liver, an exceptionally rare and irreversible cancer which strikes only 1 person in some 50,000, no more than 20-30 persons a year. Eighteen months later, on March 3, 1973, another former employee of the Louisville plant died, and a third died on December 19, 1973, again of angiosarcoma of the liver. Recognizing the rarity of the tumor and learning that all three had worked in the Goodrich PVC plant, Dr. Creech brought the matter to the attention of Goodrich, and then on January 22, 1974, to the attention of

the National Institute of Occupational Safety and Health (NIOSH).

News of other deaths followed swiftly. On January 29, 1974, Goodrich reported the death of a fourth former employee from angiosarcoma; a report of the death of a fifth employee followed on February 15th. Six days later, Union Carbide advised NIOSH of the death of one of its PVC workers from liver angiosarcoma. Goodyear Tire and Rubber Company announced a vinyl chloride worker fatality from liver angiosarcome [sic] on March 1, 1974, and reported two more such deaths from the same cause on March 22nd. Goodrich reported cases of liver angiosarcoma in two of its living employees. On April 16, 1974, Firestone Plastics announced the death of one of its employees from the same disease. Finally, on May 10, 1974, the National Cancer Institute diagnosed another Union Carbide VCM worker as a victim of the same disease. In all, the deaths of 13 workers in the PVC and fabricating industries were reported.

III.

The Secretary's Actions

Two days after Goodrich made its report to NIOSH of its first three VCM worker deaths, an inspection of its plant by NIOSH indicated considerable exposure of workers to VCM, and control procedures as well as precautionary monitoring were recommended. NIOSH alerted other federal agencies and after additional investigation soon concluded that VCM was the suspect agent for a new occupational cancer. On April 5, 1974, the Assistant Secretary of Labor, acting on behalf of the Secretary, held a hearing and promulgated an emergency temporary standard of 50 ppm TWA [1] in lieu of the pre-

[1] Time Weighted Average (TWA) represents a worker's cumulative exposure to a toxic substance during a 9-hour shift.

vailing 500 ppm one. At the hearing, industry itself showed concern, and evidence was presented that both VCM and PVC plants could reduce concentrations below 50 ppm TWA. As in the past, Dow Chemical spoke out for worker safety and urged that industry exposure be reduced to 50 ppm TWA by operational and engineering changes and that appropriate respiratory protection be given where such level was not attainable. The Assistant Secretary concluded that the evidence demonstrated VCM to be carcinogenic for man. *See* 39 Fed. Reg. 12342. Monitoring and housekeeping requirements were also imposed, and a requirement was included that, if the 50 ppm level was breached, appropriate respirators equipment be furnished workers. The emergency order was limited to six months "during which time the whole question of possible exposure of humans to VC would be reconsidered more fully and in the light of more information, including experiments which are underway at the time."

On April 9, 1974, the Industrial Bio-Test Laboratory notified MCA that its preliminary findings in their animal exposure study showed that angiosarcoma of the liver was produced in mice at a level of 50 ppm of vinyl chloride, and MCA so informed the federal government. On May 10, 1974, the Assistant Secretary again acted. Issuing a notice of proposed permanent rulemaking, he drew attention to the MCA study results and noted that: "the question of a safe level of exposure for humans cannot be determined at this time, and may continue as a matter for scientific deliberation for many years." 39 Fed. Reg. 16986. In the interim, he concluded, it was necessary to abandon the 50 ppm emergency temporary standard and to establish it at as low a level as can be detected using methodologies sensitive to 1 ppm plus-or-minus 50%, i.e., the so-called "no-detectable" level. This level was to be reached through the "institution of engineering controls and work practices as soon as feasible," but respiratory protection

was to be afforded where the goal could not otherwise be achieved.

On May 24, 1974, notice of a hearing on the proposed standard to be held before an Administrative Law Judge was given. Eight days of hearings were held during June and July of 1974, and additional materials were received from interested parties until September 25th. In addition, the record of the previous hearing on February 25, 1974, was ordered to be included.

On October 1, 1974, the final standard was promulgated, effective January 1, 1975.[2] *See* 39 Fed. Reg. 35890. The main provisions are as follows:

(1) The standard applies to manufacturers of VCM and PVC and to fabricators of PVC, but excludes those merely handling or using already-fabricated products. 29 C.F.R. § 1910.93q(a)(2).

(2) In place of the potentially obscure "no detectable level" standard, a permissible exposure limit not greater than 1 ppm averaged over an eight-hour period is set, but allows for peaks of VCM exposure up to 5 ppm during periods not exceeding 15 minutes. 29 C.F.R. § 1910.93q(c).

(3) All employers are required to conduct an initial program of monitoring and measurement of exposure levels, but need not continue monitoring if initial levels are below the so-called "action level" of 0.5 ppm averaged over the eight-hour work day. 29 C.F.R. § 1910.93q(d).

(4) The standard requires that "feasible engineering and work practice controls" be employed to reduce exposure below the permissible exposure wherever possible or to the lowest practicable level if not possible, supplemented by respiratory protection. 29 C.F.R. § 1910.93q (f)(2).

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[2] Petitioners' application for stay of the January 1st deadline was granted pending our disposition of the matter.

(5) Where respiratory protection is required under the standard, suitable equipment, as indicated by a chart in the standard, shall be provided, and use shall be required of employees unless the VCM level is below 25 ppm measured over any 15 minute period, in which case the use of respiratory equipment is optional with the employee until January 1, 1976. 29 C.F.R. § 1910.93q(g)(1).

(6) Employees working in certain hazardous operations, especially those involved in physically cleaning the interiors of PVC manufacturing reactors, shall be provided protective garments and respiratory equipment. 29 C.F.R. § 1910.93q(h).

(7) A medical surveillance program is required for all employees exposed to VCM in excess of the action level of 0.5 ppm. 29 C.F.R. § 1910.93q(k).

(8) Finally, in addition to certain record-keeping requirements, all entrances, work-areas, and containers related to VCM or PVC manufacture and PVC fabrication are required to be labelled with the warning legend: "Cancer-Suspect Agent". 29 C.F.R. § 1910.93q(1).

IV.

Petitioners' Contentions

(a)

Petitioner's initial claim is that the available scientific and medical evidence does not establish that the 1 ppm exposure level adopted by the Secretary is required by health or safety considerations. They claim that no proof exists in the record to justify such a low standard, since all of the medical witnesses testified that no one can say whether exposure to VCM at low levels was safe or unsafe. Further, they point to studies of employee health by Dow Chemical over a number of years which concluded that exposure to VCM below 200 ppm did not lead to any adverse effect.

We find, however, that the evidence is quite sufficient to warrant the Secretary's choice. First, it must be remembered that we are dealing here with human lives, and the record reveals that 11 manufacturing plant workers and two fabrication plant workers have already died from the effects of this potent chemical. Moreover, the animal exposure study, sponsored by MCA, the industry's own trade association, identified fatal liver angiosarcoma and other kidney and liver diseases at the 50 ppm level. None of the physicians or scientists who testified could identify a safe level of exposure to VCM, nor the precise mechanism by which it produces cancer; yet expert after expert recommended that this "very virulent" carcinogen be restricted to the lowest detectable level. Indeed, as one witness, Dr. Kraybill of the National Cancer Institute, testified:

> Certainly, there is little margin for safety if a response can be expected at a level below 50 parts per million which in truth is now only a fifty-fold safety factor in terms of the proposed standard. According to toxicological principles, were this compound a non-carcinogen, then to establish a tolerance or safe level, there would have to be a 100 to 1 margin of safety in terms of a no-effect level, and from the experimental data on the animals we don't even know what the no-effect level is. Obviously, this would put the allowable level at a small fraction of a given standard —of the given standard.

As in *Industrial Union Department, AFL-CIO* v. *Hodgson, supra,* the ultimate facts here in dispute are "on the frontiers of scientific knowledge", and, though the factual finger points, it does not conclude. Under the command of OSHA, it remains the duty of the Secretary to act to protect the workingman, and to act even in circumstances where existing methodology or research is deficient. The Secretary, in extrapolating the MCA study's finding from mouse to man, has chosen to reduce

the permissible level to the lowest detectable one. We find no error in this respect.

Failing in this contention, petitioners strongly urge that the Secretary breached his statutory mandate to insure that the standard selected is a "feasible" one.[3] Relying on the so-called Snell Report,[4] petitioners claim that VCM and PVC manufacturers will never be able to reduce levels of exposure to 1 ppm through engineering means. They point to the conclusion reached by the Snell Report that:

> The costs of compliance increase rapidly with decreasing VCM target levels and represent significant engineering uncertainty or infeasibility beyond 10 ppm ceiling and 2-5 ppm TWA for the VCM industry and 15-25 ppm ceiling and 10-15 ppm TWA for the PVC industry.

According to the report, "[b]ased on the industry surveys and Snell's independent assessments of the state-of-the-art of the technology," the standard price of VCM would only rise from 7.41¢ /lb. at present to 7.69¢/lb. at a target level of 2-5 ppm TWA, but would supposedly soar to 12.71¢/lb. at the "no detectable" level.

In his statement of reasons in support of the standard, the Assistant Secretary acknowledged the industry contention and the Snell conclusion about the infeasibility of

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[3] 29 U.S.C. § 655(b)(5) provides in part:

> The Secretary * * * shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity * * *.

[4] This report, "Economic Impact Studies of the Effects of Proposed OSHA Standards for Vinyl Chloride," was prepared in September of 1974 by Foster D. Snell, Inc., an independent consultant, at the request of the Secretary of Labor and estimates the cost to the industry of complying with various exposure levels between 50 ppm and 0-1 ppm. Plant and industry visits were the principal means of information gathering.

the 1 ppm level, but noted that: "Labor union spokesmen and the Health Research Group, Inc., however, have suggested that such a level is attainable." The Assistant Secretary went on to say:

> Since there is no actual evidence that any of the VC or PVC manufacturers have already attained a 1 ppm level or in fact instituted all available engineering and work practice controls, any estimate as to the lowest feasible level attainable must necessarily involve subjective judgment. Likewise, the projections of industry, labor, and others concerning feasibility are essentially conjectural. Indeed, as Firestone has suggested, it is not possible to accurately predict the degree of improvement to be obtained from engineering changes until such changes are actually implemented.
>
> We agree that the PVC and VC establishments will not be able to attain a 1 ppm TWA level for all job classifications in the near future. We do believe, however, that they will, in time, be able to attain levels of 1 ppm TWA for most job classifications most of the time. It is apparent that reaching such levels may require some new technology and work practices. It may also be necessary to utilize technology presently used in other industries. In any event the VC and PVC industries have already made great strides in reducing exposure levels. (See testimony of Dow Chemical Co., TR 973). For example, B. F. Goodrich testified (TR 1120) that it has reduce [sic] average exposure levels in several PVC plants from 35-40 ppm early this year to 12-13 ppm at the time of the hearing. We are confident that industry will continue to do so. [39 Fed. Reg. at 35892.]

We cannot agree with petitioners that the standard is so clearly impossible of attainment. It appears that they simply need more faith in their own technological potentialities, since the record reveals that, despite similar predictions of impossibility regarding the emergency 50 ppm standard, vast improvements were made in a matter of weeks, and a variety of useful engineering and work practice controls have yet to be instituted. In the area of

safety, we wish to emphasize, the Secretary is not restricted by the status quo. He may raise standards which require improvements in existing technologies or which require the development of new technology, and he is not limited to issuing standards based solely on devices already fully developed. *Cf. Chrysler Corp.* v. *Dept. of Transportation*, 472 F.2d 659, 673 (6th Cir. 1972); *Natural Resources Defense Council, Inc.* v. *E.P.A.*, 489 F.2d 390, 401 (5th Cir. 1971) [sic].

There is much testimony in the record, especially in the Snell Report, indicating that VCM concentration can be easily pinpointed and largely corrected. For example, many of the companies engaged in PVC manufacture still perform the cleaning of batch reactors by opening the vessel and having the worker physically enter it. In chipping off the accretion from the walls of the vessel, the worker is thus exposed to a high concentration of VCM. Yet other, less hazardous methods are currently available and in use, in which the vessels are cleaned by machinery, emulsions or simply water under high pressure. Other sources of exposure are encountered in filling tank cars, measuring, testing and repairing pipe joints or other connections. The Snell Report indicates that much of this may be alleviated.

But whether it can or not, the Secretary's compliance scheme does not rest only on engineering and work practice controls. He does mandate that the industry use such technology to the extent feasible, but, more importantly, he requires that, in addition, respiratory protection be used if engineering means cannot bring the VCM level down to the permissible limit.

To be sure, respirators have their drawbacks. These problems were detailed at the hearings and recognized by the Assistant Secretary. Self-contained and air-hose type breathing equipment is bulky, expensive, and infeasible for full-time use, as well as potentially hazardous in terms of tripping, restricted mobility, and over-exhaustion of work-

ers. But the fact remains that they effectively eliminate exposure to VCM, and they are already being used by some PVC companies in the cleaning process and at other points in production with good success.

Like the industry's claims about the impossibility of achieving compliance through technological means, petitioners' claims of dire consequences from the requirement of respiratory protection are exaggerated. It does not appear that full-time use of respirators is necessary, and the Snell Report points this out. Furthermore, lightweight, inexpensive cartridge or cannister-type respirators, which can effectively filter out VCM at low levels, are now available and acceptable. Contrary to petitioners' assertions, the Snell Report indicates that a variety of respirators are reasonably available.

c.

We find that the Secretary's directions are clear, definite, and certain and that they are also entirely feasible, since the goal of the lowest detectable level can definitely be attained through the combination of technological means and respirators. Our conclusion in this regard is buttressed by the fact that only some 6,500 of the workers coming under the standard—those in the VCM and PVC manufacturing field —are potentially exposed to high or constant VCM concentrations, and only a small percentage of them are actually subject to excessive concentrations of the chemical during manufacture. The remaining hundreds of thousands of workers are in the fabrication field where exposure is already so low that some of the petitioners claim that the fabricators should not even be under the standard; these, of course, have been included because of their work with PVC resin which in final form contains residual amounts of VCM, and the record shows that two deaths have in fact occurred among fabricators.

If, in the future, the monitoring under the standard indicates that the VCM level among fabricators is sufficiently

low and that the sporadic, unpredictable exposure of these workers to residual VCM has been controlled, the fabricators might well be excluded or included in a separate, less rigorous standard. Certainly if PVC producers were able to eliminate all residual VCM from the resin before it is delivered to the fabricator, there would seem to be no reason for their inclusion. But this would be for the Secretary to decide on appropriate application or on his own motion, and, as the record presently stands, their inclusion is amply justified.

In any event, compliance is time-phased and, if the petitioners find that they cannot comply for reasons beyond their control, OSHA permits the amendment of standards. *See* 29 U.S.C. § 655(b)(6)(A). Upon application and sufficient proof of such a situation, we feel certain that the petitioners would obtain relief at the hands of the Secretary. This is especially true of the "cancer suspect agent" labelling requirements which petitioners urge are beyond statutory contemplation. We think that the Secretary is simply "fighting fire with fire" and using the labels to bring the danger of vinyl chloride forcibly to the attention of the workers. *Cf. Synthetic Organic Chemical Mfrs. Assn.* v. *Brennan*, 503 F.2d 1155 (3d Cir. 1974). They deserve no less treatment. We have also considered the other arguments of the petitioners and find them untenable.

V.

It is our conclusion that the challenged aspects of the Secretary's vinyl chloride standard are supported by substantial evidence in the record and that the petitions for review must be denied. Taking into account the delay occasioned by these petitions, we think that a reasonable "lead time" is appropriate and therefore order that the Secretary's regulations, rather than being effective January 1, 1975, shall become effective sixty days after the date of this order and that the time requirement as to respiratory protection contained in 29 C.F.R. § 1910.93q(g)(1) is re-scheduled accordingly.

Judgment Sought To Be Reviewed

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

At a Stated Term of the United States Court of Appeals, in and for the Second Circuit held at the United States Court House, in the City of New York, on the thirty-first day of January, one thousand nine hundred and seventy-five.

Present:

Hon. Tom C. Clark, Associate Justice	74-2284	74-2450
Hon. Frederick vP. Bryan, District Judge	74-2286	74-2491
Hon. Kevin T. Duffy, District Judge	74-2308	74-2585
	74-2345	74-2609
	74-2449	

[Names of Parties deleted in reproduction]

Petitions to review an order of the Occupational Safety and Health Administration.

These causes came on to be heard on a certified list of items comprising the record of the Occupational Safety and Health Administration and was argued by counsel.

On consideration thereof it is hereby ordered, adjudged and decreed that the petitions for review be and they hereby are denied in accordance with the opinion of this court with costs to be taxed against the petitioners.

A. DANIEL FUSARO,
Clerk

APPENDIX B

REGULATION INVOLVED

Occupational Safety and Health Standard

The Preamble and Order promulgating the Occupational Safety and Health Standard for Vinyl Chloride, 29 C.F.R. § 1910.93q (39 Fed. Reg. 35890, October 4, 1974), as amended (39 Fed. Reg. 41848, December 3, 1974), provide as follows:

TITLE 29—LABOR

CHAPTER XVII—OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, DEPARTMENT OF LABOR

PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

Standard for Exposure to Vinyl Chloride

Pursuant to sections 6(b), 6(c), and 8(c) of the Occupational Safety and Health Act of 1970 (84 Stat. 1593, 1596, 1599; 29 U.S.C. 655, 657) Secretary of Labor's Order No. 12-71 (36 FR 8754) and 29 CFR Part 1911, § 1910.93 of Part 1910 of Title 29, Code of Federal Regulations is hereby amended in the manner set forth below, in order to provide an Occupational Safety and Health standard dealing with the exposure of employees to vinyl chloride.

I. *Background*—(1) *Vinyl chloride.* Vinyl chloride (chloroethene), Chemical Abstracts Service Registry No. 75014, is a synthetic organic chemical made from ethylene or acetylene and chlorine by any of several processes. It is the parent compound of a series of thermoplastic resin polymers and copolymers which are widely used for containers, wrapping film, electrical insulation, pipe, conduit, and a variety of other industrial and consumer products. Vinyl chloride has been made commercially in this country since 1939, and present production is in excess of seven billion pounds per year. The vinyl chloride industry divides into three segments: monomer production, polymer production, and fabrication. Production of the monomer

is a large-scale continuous process, involving only a few firms. There are comparatively few employees in this segment of the industry, because the processes lend themselves to automation.

Vinyl chloride (VC) is used primarily in the production of polyvinyl chloride (PVC), a resin which is produced through batch processing. The conversion of the VC monomer into a polymer or copolymer is an incomplete process, i.e., not all of the monomer is reacted.

PVC is fabricated by a variety of techniques, including extrusion, injection molding and calendering, to form a finished product that needs no further chemical handling. The vast majority of employees involved in the VC industry are employed by fabrication firms. Such firms range in size from those with few employees and simple equipment to large plants involving many employees and considerable capital.

Vinyl chloride (VC), a gas at ambient temperature and pressure, is a chlorinated hydrocarbon, which heretofore has been regarded as having moderate liver toxicity. The initial standard, contained in Table G-1 of 1910.93, established a ceiling value of 500 parts of VC per million parts of air.

(2) *The emergency temporary standard.* On January 22, 1974, the Occupational Safety and Health Administration (OSHA) was informed by the National Institute for Occupational Safety and Health (NIOSH) that the B. F. Goodrich Chemical Company had reported that deaths of several of its employees from a rare liver cancer (angiosarcoma) may have been occupationally related. As a result of this notification and after consultation with NIOSH, and a joint inspection of the B. F. Goodrich plant by OSHA, NIOSH and the Kentucky Department of Labor, a fact-finding hearing was announced on January 30, 1974 (39 FR 3874) and held on February 15, 1974.

Information obtained from this hearing, particularly the preliminary reports of experiments conducted by Professor Cesare Maltoni of the Instituto di Oncologia, Bologna, Italy, demonstrated that vinyl chloride induced angiosarcoma in rats at levels as low as 250 ppm, and in other species at higher levels. Experiments performed at lower levels of exposure were not completed at that time. Other testimony from medical witnesses and NIOSH, and the results of autopsies, led to the conclusion that the Goodrich workers had angiosarcoma of the liver and that VC probably was the causal agent in the angiosarcomas observed.

In post hearing comments, additional angiosarcoma deaths were reported among workers who had been exposed to VC in plants operated by Union Carbide Corporation, Firestone Plastics Corporation and Goodyear Tire & Rubber Company.

On the basis of all information available at that time, and the fact that employees were being exposed at levels around the experimentally observed effect level of 250 ppm, an emergency temporary standard (ETS) was promulgated on April 5, 1974 (39 FR 12341) pursuant to section 6(c) of the Act, as 29 CFR 1910.93q.

This standard reduced the permissible exposure level from a ceiling of 500 ppm to a 50 ppm ceiling, and established other requirements, including, for example, monitoring and respiratory protection. It was expressly recognized that this standard limiting exposures to a 50 ppm ceiling was a tentative, interim standard, and that the whole question of exposure to VC would be considered more fully in the light of additional information, especially the results of experiments which were known to be underway at that time.

On April 15, 1974, information and data were presented to representatives of OSHA, NIOSH, and the Environ-

mental Protection Agency by the Industrial Bio-Test Laboratories, Northbrook, Illinois, concerning results of animal exposure studies with VC. These studies were sponsored by the Manufacturing Chemists Association. Although only preliminary in nature at that time, these results revealed that 2 out of 200 mice exposed to VC concentrations of 50 ppm for 7 hours a day, five days a week, for approximately 7 months, had developed angiosarcoma of the liver.

(3) *The proposed permanent standard.* Based on the demonstrated evidence of VC's carcinogenicity in three animal species (rats, mice and hamsters), and the substantial probability that VC had been the causal agent in the cases of liver angiosarcoma found in workers both here and abroad, OSHA proposed to revise 1910.93q and published a comprehensive proposal (39 FR 16896) on May 10, 1974, to protect employees from hazards of exposure to VC. The proposal called for limitation of employee exposure to VC to "no detectable level," as measured by a sampling and analytical method sensitive to 1 ppm, with an accuracy of 1 ppm ±50 percent. The proposal also called for the establishment of regulated areas and limited access to such areas to authorized persons. A requirement for monitoring of employee exposures was proposed, along with engineering and work practice controls to be implemented when exposures over the detectable limit were measured.

Respiratory protection would have been required while engineering and work practice controls were being implemented or where exposures exceeded the permissible limit even after feasible engineering controls were instituted.

In addition, the proposed standard included requirements for medical surveillance, protective clothing, emergency procedures, training, specific protection during maintenance and decontamination operations, transportation loading and unloading operations and record-keeping.

(4) *Hearing on the proposal.* The proposal, as published on May 10, 1974, allowed 30 days for interested parties to submit written comments and to request an informal rulemaking hearing. Informal contacts with OSHA staff and early responses indicated that the subject was of great interest and importance to many persons. Because of the limited time available before expiration of the six month period provided in section 6(c)(3) of the Act for promulgation of a final standard, it was decided to hold a hearing as soon as possible. Accordingly, on May 24, 1974, a notice of a hearing was published (39 FR 18303), setting a hearing date of June 25, 1974. The hearing was conducted from June 25 through June 28, and again from July 8, through July 11, before Administrative Law Judge Gordon J. Myatt. All participants were given the opportunity to present testimony and to cross-examine other witnesses. Persons participating in the hearing were given until August 23, 1974, to file additional posthearing comments, including various items of information which were requested during the examination of witnesses.

(5) *Economic and technical impact study.* During the hearing, OSHA determined that additional facts would be needed to determine the practicality of certain aspects of the proposed standard. Accordingly, OSHA contacted an independent consultant, Foster D. Snell Corporation, to conduct studies of the feasibility of compliance at various exposure levels, including those proposed by OSHA and others advanced by industry spokesmen. Snell was also commissioned to collect information regarding the economic costs of compliance. This action was announced at the close of the hearing, and Judge Myatt further announced that the record would be kept open for a period of time beyond August 23, to allow interested persons to comment in writing on the study. On August 26, 1974, OSHA announced that the preliminary study was available and that comments were to be submitted no later than September 6, 1974 (39 FR 30844). On September 13, 1974, OSHA

invited comments on both the preliminary and the final study, which was to be received on or before September 25, 1974 (39 FR 33009).

(6) *Environmental impact statements.* A notice of intent to file an environmental impact statement assessing the impact of a proposed standard on occupational exposure to VC was published in the FEDERAL REGISTER on April 24, 1974 (39 FR 14522). The notice invited any person having information or data on the environmental impact to submit it to OSHA by May 17, 1974. On June 12, 1974, a draft environmental impact statement was prepared and circulated to all interested persons. Ten copies were forwarded to the Council of Environmental Quality (CEQ), which published a notice of its filing and availability in the FEDERAL REGISTER on June 25, 1974 (39 FR 22975). A 45 day period was allowed for the submission of comments on the draft statement. On September 5, 1974, the final environmental impact statement was prepared and a copy of it and all substantive comments were sent to appropriate governmental agencies, private organizations, and other interested persons. CEQ published a notice of availability for the final statement on September 6, 1974 (39 FR 32350). The submission of comment was invited until September 25, 1974. The final statement and all significant comments have been carefully considered in arriving at the final standard on occupational exposure to VC.

(7) *The record.* The record in this proceeding is one of the most exhaustive ever relied upon by OSHA. It consists of pre and post-hearing comments and testimony received at both factfinding and rulemaking hearings, the studies and inspections conducted by OSHA personnel, the environmental impact statements, the economic and technical impact studies, and all other relevant information. In all, over 600 written comments have been received, with more than 200 separate oral and written submissions made

with regard to the two hearings. The record itself exceeds 4,000 pages. Employers, employees, labor unions, public health groups, independent experts, physicians, research scientists, and specialists in many fields have been invited to submit information and have made their views, knowledge and expertise available to OSHA. The entire record encompassing these submissions was thoroughly reviewed and evaluated in reaching the determinations set forth below.

II. *Findings regarding carcinogenicity, exposure levels and feasibility*—(1) *Carcinogenicity of vinyl chloride.* The carcinogenicity of vinyl chloride for three animal species (rat, mouse, hamster) has been documented on the record by the studies of Maltoni and Bio-Test Laboratories. Moreover, Maltoni's investigations have demonstrated a dose-dependent relationship for induction of tumors (i.e., more tumors occur at higher exposure levels), including angiosarcoma of the liver, in rats. The investigations of Industrial Bio-Test Laboratories have demonstrated a similar relationship for both rats and mice. These investigators have induced angiosarcoma of the liver in rats and mice at exposure concentrations of 50 ppm, and in hamsters at higher concentrations of exposure. Additional tumors involving other organs, including the kidneys, lungs, and skin of exposed animals, were also observed in frequencies much in excess of control animals. The incidence of tumors in mice in the Industrial Bio-Test Laboratories investigations is particularly pertinent. Of 200 mice (100 males, 100 females) exposed to 50 ppm of vinyl chloride by inhalation for eleven months, 100 died. Sixty-four animals died without gross postmortem pathologic examination being performed. Of the 36 remaining animals for which a gross postmortem pathologic examination was performed, 13 (36 percent) were found with liver tumors (including angiosarcomas) 21 (58 percent) with lung tumors, 9 (25 percent) with skin tumors, and one with a kidney tumor.

According to the 1970 report by the Surgeon General's Ad-Hoc Committee on the Evaluation of Low Levels of Environmental Chemical Carcinogens, the finding of cancer in two or more animal species may be extrapolated to indicate a carcinogenic hazard to humans. Here, such a finding was made in three species that were exposed to VC by inhalation—a route comparable to employee exposure. In addition, there were at least 13 confirmed cases of angiosarcoma of the liver among employees exposed to VC, a particularly significant number in view of the extreme rarity of this cancer in the U.S. adult male population (testimony of Dr. Marcus Key, Director of NIOSH, at the rulemaking hearing).

The findings of angiosarcoma of the liver in both experimental animals and exposed employees is compelling evidence that exposure of humans to vinyl chloride induces this tumor. Industry spokesmen, at the hearing, conceded that VC is carcinogenic for humans (e.g., testimony of Dr. McBurney, Rulemaking hearing, 1041). Accordingly, it is concluded that VC must be regarded as a human carcinogen, and the probable causal agent of angiosarcoma of the liver, and that exposure of employees to VC must be controlled.

Additional evidence of tumor induction in a variety of other organs, including lung, kidney, brain and skin, as well as non-malignant alterations, such as fibrosis and connective tissue deterioration, indicates additional oncogenic and toxicologic properties of vinyl chloride, which must be considered in establishing control regulations. (See testimony and results of studies by Bio-Test Laboratories, Tabershaw-Cooper, Maltoni, NIOSH, and Selikoff.)

(2) *Exposure limits.* Upon finding that exposure of employees to vinyl chloride may create a carcinogenic hazard, the amount of exposure which is hazardous must be determined. The Surgeon General's Ad Hoc Committee referred to above concluded that safe exposure levels for

carcinogenic substances cannot be scientifically determined. This position is supported by the testimony of NIOSH at the hearing, its recommendations for a standard of no detectable level, and by the testimony of expert witnesses from the National Cancer Institute.

Several witnesses and persons who submitted comments have taken a contrary view and have suggested that man is less sensitive to biologic aberrations induced by vinyl chloride exposure than experimental animals. Proponents of this position have argued that if humans were as sensitive as rodents, an "epidemic" of cancer resulting from VC exposures should have already been discovered among employees. They also argue that the employees in whom tumors have been observed are those who have considerable employment experience as polymerization reactor cleaners. Because it is generally agreed that reactor cleaning involved high exposures to vinyl chloride in years past, it is argued that the lower levels currently found in the workplace have not induced cancer and are therefore safe. We reject this argument.

The fact that approximately three-quarters of those employees with the longest exposure to VC (greater than 20 years since initial exposure) have not yet been located, makes it impossible to determine the actual number of affected employees. The cases of liver tumors observed to date have an average latency period, since initial exposure, of approximately 20 years. If it is assumed that induction of angiosarcoma is a dose-related phenomenon, and if employees engaged in cleaning reactors did, in fact, receive larger doses of vinyl chloride, it would be expected that such tumors would be observed earlier for this employee population. For this reason, the significance of presumed lower doses cannot be accurately assessed until a longer period of time has passed, as a longer induction period would be expected.

Initiation of exposure to chemical carcinogens and induction of cancer are not necessarily synchronous events.

Because of the physiologic complexities involved with carcinogenesis, induction of tumors does not occur in all employees with similar exposure histories. For example, Dr. Schneiderman of the National Cancer Institute emphasized during his testimony that only about a fifth of longer-term heavy smokers develop lung cancer. Accordingly, the industry contention that exposure levels have been dramatically reduced since the 1940's is not reliable evidence that current levels of exposure are safe.

Some industry spokesmen also suggested that the apparent nonrandom distribution of observed cancer in employees may indicate an exposure threshold for tumor induction, based on variations in the workplace design or practice and resultant employee exposures (testimony and questioning by Tenneco Chemicals, Inc.). It has also been emphasized that in only 3 of 8 polymerization plants where employees have been exposed to VC for more than 20 years have any employees developed angiosarcoma of the liver. This argument is very similar to that raised concerning variability of past employee exposure. Although geographic and workpractice differences may ultimately be demonstrated to be factors in distribution of angiosarcoma, sufficient information is unavailable to exclude from consideration of risk those employees in workplaces for which cases of angiosarcoma have not been observed.

It has also been suggested that the absence of cancer in a population of 335 Dow Chemical Company polymerization employees monitored over a period of 7 years, indicates that exposure to vinyl chloride at concentrations of less than 200 ppm is safe. (See Study by Dr. Cook, submitted at the hearing by Dow Chemical Company.) However, the group surveyed did not include all workers who had been exposed, and the missing employees included many who had the longer term (over 20 years) exposures. Moreover, the statistically insignificant size of the sample population decreases the possibility that tumors would be observed.

Dow also presented preliminary data in testimony at the hearing on the possible metabolic pathways of VC. The hypothesis presented was that VC may exert its carcinogenic effect by a metabolite, and that the metabolite is produced only when VC is metabolized by a secondary metabolic pathway operating only when enzymes regulating the primary pathway are saturated, as would be the result at higher exposures. The preliminary data indicated the possibility of an additional pathway for metabolism of VC in rats exposed to concentrations of VC in excess of 220 ppm. However, the occurrence of angiosarcoma in both rats and mice at VC exposure concentrations of 50 ppm indicates that if a metabolite of VC is the ultimate carcinogen, then it must be generated at lower exposure concentrations in these species. Although this research may be helpful to the thorough understanding of the carcinogenicity of VC, it appears that it does not yet offer evidence which can assist in determination of safe exposure concentrations for employees, or even that such safe exposures exist.

A number of witnesses representing employers have stressed that there is no evidence of cancer, either in employees or experimental animals, at exposure concentrations of VC less than 50 ppm. (See e.g., testimony of Firestone, Tenneco Chemicals.) The conclusion of these witnesses was that no decision can be made concerning risk of exposure to VC at concentrations less than 50 ppm.

On the other hand, the testimony of most expert witnesses, including some industry biomedical experts, stated that quantification of a safe exposure concentration is not possible with the present state of scientific knowledge. (See e.g., testimony of Selikoff, Firestone, NCI, and NIOSH.)

In our view, the demonstration of cancer induction in humans at a particular level is not a prerequisite to a determination that a substance represents a cancer hazard for

humans at that level. It would be imprudent to assume man to be less sensitive to VC exposure than experimental animals in the absence of conclusive evidence. It would also be unfounded to assume that animals will not develop tumors when exposed at concentrations of VC of less than 50 ppm. Should a sufficiently large number of experimental animals be exposed to VC at concentrations of less than 50 ppm, Schneiderman said that it would be expected that some would develop VC induced tumors.

(3) *Feasibility.* There is virtually no dispute that most, if not all, fabricators are currently capable of reaching exposure levels of 1 ppm through engineering controls. These employers employ well over 95 percent of all employees exposed to VC. Indeed, several fabricators are already operating at this level (see SPI testimony). However, industry spokesmen have universally claimed that it is infeasible for the VC and the PVC industries to remain below 1 ppm consistently, using engineering controls. In addition, the Snell study on technical feasibility concluded that a 1 ppm ceiling is not feasible for the VC and PVC industries with present technology, but that the VC industry could currently attain lower exposure levels than the PVC industry. Labor union spokesmen and the Health Research Group, Inc., however, have suggested that such a level is attainable.

Since there is no actual evidence that any of the VC or PVC manufacturers have already attained as 1 ppm level or in fact instituted all available engineering and work practice controls, any estimate as to the lowest feasible level attainable must necessarily involve subjective judgment. Likewise, the projections of industry, labor, and others concerning feasibility are essentially conjectural. Indeed, as Firestone has suggested, it is not possible to accurately predict the degree of improvement to be obtained from engineering changes until such changes are actually implemented.

We agree that the PVC and VC establishments will not be able to attain a 1 ppm TWA level for all job classifications in the near future. We do believe, however, that they will, in time, be able to attain levels of 1 ppm TWA for most job classifications most of the time. It is apparent that reaching such levels may require some new technology and work practices. It may also be necessary to utilize technology presently used in other industries. In any event, the VC and PVC industries have already made great strides in reducing exposure levels. (See testimony of Dow Chemical Co., TR 973). For example, B. F. Goodrich testified (TR 1120) that it has reduced average exposure levels in several PVC plants from 35-40 ppm early this year to 12-13 ppm at the time of the hearing. We are confident that industry will continue to do so.

(4) *Conclusions.* The conclusions below are based on a thorough review and evaluation of all the evidence submitted. Where decisions can be based on record evidence, this has been done. Where, however, factual certainties are lacking or where the facts alone do not provide an answer, policy judgments have been made.

There is little dispute that VC is carcinogenic to man and we so conclude. However, the precise level of exposure which poses a hazard and the question of whether a "safe" exposure level exists, cannot be definitively answered on the record. Nor is it clear to what extent exposures can be feasibly reduced. We cannot wait until indisputable answers to these questions are available, because lives of employees are at stake. Therefore, we have had to exercise our best judgment on the basis of the best available evidence. These judgments have required a balancing process, in which the overriding consideration has been the protection of employees, even those who may have regular exposures to VC throughout their working lives.

Based on the available evidence and in view of the above considerations, including feasibility, we believe that em-

ployee exposures to VC must be reduced to a 1 ppm time-weighted average (TWA). We also believe that PVC and VC establishments will, in time, be able to attain that level through engineering controls, and that fabricators can do so in the immediate future.

In addition to the TWA requirement, we have established a 5 ppm ceiling (averaged over a 15-minute period) in order to prevent exposure of employees to unacceptably high excursions. From an operation standpoint, this ceiling level is realistic because minor excursions up to the ceiling level are likely to occur on a regular basis.

III. *The final standard*—(1) *Scope and application.* Both the ETS and the proposal would apply the standard to the entire VC industry, including manufacturers of VC and PVC and fabricators, but excluding employers handling or using fabricated products made from VC.

There is no dispute that a standard is required for the monomer and polymer industries. However, the Society of Plastics Industry (SPI) and various fabricators (see testimony of Goodyear, General Cable, etc.) recommended that fabricators be excluded from the standard, or that a separate requirement be established for them because many of them were already at or below the proposed ceiling level.

The record evidence establishes that at least some employees in the fabricating industry are exposed in excess of the permissible control limits (See NIOSH testimony, TR 106; Robintech TR 642). In these circumstances, we believe that it is imprudent to grant a blanket exemption for all fabricators. Therefore, the final standard is applicable to the fabrication industry as well as the monomer and polymer industries. Employers who, in fact, are substantially below the exposure limit will be subjected to only minimal burdens by virtue of the "action level" to be discussed below.

Where employers in the fabricating industry have exposures approaching the permissible limit, they will appropriately be subject to the standard. Employers handling or using fabricated products made of PVC were not included in the ETS or the proposal and are excluded from the final standard. This conclusion is based on the absence of adequate evidence of exposure to VC in these operations. The final standard clarifies the exemption by defining a fabricated product as a product made wholly or partly from PVC which does not require further processing at temperatures, and for times, sufficient to cause mass melting of the PVC. SPI and others (cf. TR. 344) requested that PVC resins with less than 0.1 percent residual monomer be exempted from the regulation now, and that the exemption level be reduced to 0.01 percent in three years. SPI suggested that the exemption of materials with less than 0.1 percent of 14 carcinogens from 29 CFR 1910.93p (39 FR 3756) was an appropriate precedent. The cases are not comparable, because no attempt had been made to set air concentration limits for the 14 carcinogens. The record did not include information that reliable monitoring and measuring techniques were available. Moreover, the exemption did not exempt airborne traces of carcinogens. The administrative cutoff was provided to avoid regulation of materials about which there was no health hazard information, and which would have broadly extended the application of the regulation beyond the record. Herein, no information was presented to show safe concentration results from the use of resins with specific levels. Indeed, the proposal to change the level later, when improved technology would permit such reduction, would seem to indicate that SPI has doubts about the safety of 0.1 percent residue level. Diamond Shamrock (Exhibit 142) testified that there is no direct relation. They indicate that the airborne concentration is more related to the physical form of the resin and the ventilation provided. Also, monitoring data from industry (cf. Exhibits 131, 168, 170) and

OSHA (Exhibit 151) indicate that levels in excess of 1 ppm may be found in fabrication operations. In view of these facts and of the opportunity for employers to discontinue many duties upon a showing of no exposures above the action level, it does not appear that any residue exemption is either justified or necessary at this time. This course also agrees with a number of industry proposals (cf. TR 660).

SPI (TR 345), among others, asked that compounded PVC pellets be exempted from the standard on the grounds that the pellets had too low a residue to cause harmful or measurable emissions. While it appears that PVC pellets would have a lower residue level than virgin PVC, the fact that the pellets must be heated to a molten mass at the same temperature as PVC, for further processing, indicates that a potential for release of the residue still exists. It appears that the exemption of fabricated products should be limited to just those items which will not undergo such mass heating. Further, the opportunity to demonstrate that exposures are below the action level, and thus, discontinue many duties of the standard, provides a more positive control and an adequate relief.

(2) *Permissible exposure limit.* The standard sets an exposure limit of 1 ppm averaged over any 8 hour period, and a ceiling of 5 ppm averaged over any period not exceeding 15 minutes.

As more fully discussed above, this limit is based on an evaluation of the best available evidence and on a judgment that the health and safety of employees must be protected to the fullest extent feasible. In view of the fact that releases of VC in the VC and PVC manufacturing processes are variable, the 1 ppm ceiling level provided in the proposal would require maintenance of an average level significantly more difficult to attain through feasible engineering controls. Therefore, the exposure limit prescribed in the proposal has been rejected.

(3) *Action level.* The final standard, *unlike the ETS* and the proposal, provides for an "action level" of 0.5 ppm TWA, one-half of the permissible exposure limit. The purpose of the action level is to minimize the impact of the standard on the employers who have attained exposure levels well below the permissible limit. Thus, where the results of monitoring under paragraphs (d)(1) or (d)(2) demonstrate that no employee is exposed in excess of 0.5 ppm TWA, employers may, in effect, be exempted from some provisions of the standard. For example, fabricators who are below the action level are not required to provide medical surveillance or to monitor again, unless the employer has reason to suspect that any employee is exposed in excess of the action level. In our judgment, exposures below the action level do not present a sufficient hazard to warrant application of the entire standard to the many employers who are or will be below that level.

(4) *Monitoring.* The final standard, like the proposal, requires that individual employee exposure levels be determined. This may be accomplished by personal or area monitoring. Some witnesses and persons who submitted comments did not understand the meaning of the term "95 percent confidence level" in the proposal. Essentially it means that the employer is required to take a sufficient number of measurements so that the results obtained are statistically valid. We have modified the proposal to establish accuracy range requirements for various measurement levels. These ranges are narrow enough to ensure that a determination of compliance can be made, and broad enough to allow the application of a variety of technologies.

All covered employers are required to conduct initial monitoring. Where monitoring and measuring results are at or below the action level, no further monitoring is required unless the employer has reason to suspect that any employee is exposed in excess of the action level, or unless changes have been made in production, process, control, type of resin, etc.

Where the exposure level, without regard to respirators, exceeds the permissible levels, monitoring must be conducted at least monthly. Where exposures are less than the permissible levels, but greater than the action level, monitoring must occur at least quarterly.

(5) *Methods of compliance.* The standard, like the proposal, requires that employers immediately institute feasible engineering and work practice controls to reduce exposures to at or below the permissible exposure limit.

Where feasible engineering and work practice controls will reduce exposures below the permissible levels, they must be instituted. Where such controls will not reduce exposures below the permissible level, they must nonetheless be implemented to reduce exposures to the lowest practicable level, and be supplemented by the use of respirators to provide the necessary protection. Thereupon, a continuing program of engineering and work practice controls must be instituted to reduce exposures to the lowest practicable level. When exposures are at or below the permissible exposure limits, the program may be discontinued.

In addition, a plan for achieving control by engineering and work practice methods must be drawn up and be made available, upon request, to representatives of OSHA and NIOSH.

We recognize that many employers covered by the standard can not currently achieve compliance with the permissible exposure limit solely by the use of feasible engineering and work practice controls. The record also reflects broad generic distinctions between the compliance capabilities of the VC and PVC industries. Some industry spokesmen, including SPI (TR. 358-362), recommended that a schedule of different permissible exposure limits and compliance dates be established for the VC and PVC segments of the industry.

This view assumes that the ability and the time required to feasibly reach increasingly lower control levels is similar within each industry, but differs markedly between industries. While the record does suggest that such differences do exist between industries, as noted above, it is clear that intra-industry differences also exist. Thus, the ability and time required by each employer to attain lower control levels may depend upon such factors as the climate in which the plant is located, the age of equipment, the size of reactors, or the type of resin manufactured or used. (Snell study. Firestone testimony, etc.)

Monitoring data also tends to support such intra-industry variations. (See, e.g. Dow, Firestone, Tenneco.)

As noted above, the standard requires all employers to institute feasible engineering controls to the fullest extent and to continue to improve and apply engineering controls until full compliance is achieved.

We have not established any deadlines for full compliance through engineering controls because we are presently unable to determine when it will be feasible for most establishments to reduce exposure levels to the permissible level.

We also believe that the requirement that each employer reduce airborne concentrations to the permissible level, or to the lowest level feasible as soon as practicable will provide for inter-industry and intra-industry technological differences which do exist, and will avoid the setting of separate industry standards on the basis of the general situation and conditions in each industry.

(6) *Regulated areas.* The proposed standard would have required that regulated areas be established, that access be limited to authorized employees, and that daily rosters or summaries of those entering be kept for at least 20 years. In objection to these requirements, it was asserted that such control of access was not necessary from a health

standpoint. Secondly, it was claimed that these controls would interfere with operations by preventing access of needed employees or non-employees, such as contractors, truck drivers, customers and consultants.

The purpose of establishing regulated areas in the proposal was to limit the risk of exposure to as few employees as possible. This concern is still paramount, and thus the limited access feature remains. The final standard amends the proposal slightly to allow "authorized persons" to enter regulated areas. This change, it is felt, will allow operations to continue without undue interference. The final standard has also increased the length of time daily rosters must be maintained from 20 to 30 years. This change was based largely on epidemiological considerations. (See NIOSH testimony, tr. 119.)

(7) *Respiratory protection.* The final standard, like the proposal, requires the use of respirators where employee exposures exceed the permissible control level. Industry representatives made a number of objections to proposed requirements for respiratory protection. They stated that the "no detectable level" would effectively require continuous wearing of respirators in PVC and VC plants, and that this is not feasible because respirators are cumbersome, present a safety hazard, and employees would not use them.

We would agree that respirators have many drawbacks; the proposal did not contemplate them as a final solution. The record shows that the PVC industry particularly may need several years before plant environmental levels can be reduced so that respirators are necessary only occasionally. However, we cannot agree that respiratory protection should not be required simply because it is inconvenient, may require additional personnel, interferes with production, or may require extensive retraining of employees and restructuring of work practices. We have carefully considered all the objections, and have concluded that if the

environmental level is not controlled to the permissible exposure limit, then employees must be afforded respiratory protection.

While exposures in excess of the permissible level do constitute a hazard, we believe that it is necessary to mitigate some of the problems associated with implementing a program of respiratory protection while employees are being fitted and trained in respirator use, and while other adjustments which may be required are implemented. Therefore, until January 1, 1976, where exposures are not in excess of a 25 ppm ceiling, each employer must provide each employee with an appropriate respirator. However, employees whose exposures do not exceed a 25 ppm ceiling, may decline to use the respirator, in which case the employer is not obligated to require its use. During this adjustment period, employees will be trained in the uses, purposes and limitations of respirators, and the hazards of exposure to vinyl chloride. Moreover, each employee will be notified in writing if he has been exposed in excess of the permissible exposure limit.

Where exposures exceed a 25 ppm ceiling, respiratory protection is mandatory in light of our judgment that much greater risks are associated with such exposures.

The provisions in the final standard regarding the selection and use of respiratory protective devices differ from those in the proposal. The descriptions of atmosphere-supplying respirators have been revised to indicate more clearly the types of devices intended, and the maximum permissible concentration level for each device. Moreover, the number of types of atmosphere-supplying devices has been increased.

At the hearing Mr. Edwin C. Hyatt, an OSHA consultant, made suggestions regarding the use of particular respiratory devices. We have concluded that his suggestions are meritorious. Therefore, the provisions for selection of

atmosphere-supplying devices follow closely the recommendations contained in his testimony. Industrial spokesman also agreed. (TR with Hyatt's suggestions. (See e.g. testimony of SPI and B. F. Goodrich) (TR 85 ff) We had originally omitted air-purifying respirators because none had been approved by NIOSH for use against VC, principally because they lacked indicators to signal the expiration of the service life of the sorbent. Hyatt and other witnesses discussed in detail the desirability of being able to use canisters or cartridge air-purifying respirators, provided a sorbent could be shown to effectively absorb vinyl chloride with an adequate service life. Recently, OSHA has received respiratory data from laboratories regarding the effectiveness of commercially available canisters and cartridges for vinyl chloride. These evaluations were conducted separately by NIOSH and by the B. F. Goodrich Company and submitted to OSHA in post-hearing comments. The results indicate that certain presently available canisters and cartridges effectively absorb vinyl chloride at relatively low concentrations. In discussions of these findings with NIOSH, it has indicated that it is willing to consider on an expedited basis the approval of air-purifying respirators for use against VC. Consequently, we have included three types of air-purifying respirators in the list of acceptable units, subject to the approval of such units by NIOSH. The maximum concentration for which each respirator may be used is based upon our evaluation of the data submitted by NIOSH and Goodrich. Because air-purifying respirators do not indicate sorbent exhaustion or breakthrough of VC, and because VC has no inherent warning properties at levels for which these devices are used, strict administrative controls will be required for their use. Such controls include a program to assure timely replacement of canisters or cartridges and an alarm system to alert employees when vinyl chloride concentrations exceed the concentrations allowed for the particular type of respirator in use.

(8) *Hazardous operations.* This is a new section within the final standard. It encompasses essentially the proposal's requirements for maintenance and decontamination but has restated them in terms of performance language to allow greater flexibility for employers to deal with such operations. The intent of the new section is to protect employees engaged in activities that present a risk of exposure to vinyl chloride in excess of the permissible levels. An example would be the cleaning of a filter where resin containing high residual monomer is trapped.

The proposal's requirement for full-body, impervious clothing has been replaced by the direction to use impervious garments suited to the particular situation and probable extent of exposure. Thus, full-body clothing is not always necessary, and is therefore not required where less protection is adequate. Since vessel entry falls within the definition of a hazardous operation, the vessel entry section of the proposal has been deleted from the final standard.

(9) *Emergency situations.* The definition of emergency has been recast in terms of an unexpected massive release. The main objection to the section on emergency situations in the proposal was that, as the term was defined, many ordinary leaks or operations resulting in a small release of vinyl chloride would be considered emergencies. This was not the intent of the proposal. The final standard has been clarified to correct this ambiguity. It should be noted that the written operational plan required by the standard need not be developed for minor excursions above the permissible exposure limit, and that such excursions need not be reported.

(10) *Signs and labels.* The thrust of the signs and labels section is to apprise employees of the cancer and fire hazards. No objections have been raised with respect to informing employees of the fire hazard. However, a number

of objections were raised at the hearing and in written submissions to the requirement that the word "cancer" appear on all signs and labels. The principal argument advanced against its use was that the term "cancer" or "cancer-suspect agent" scares employees and that instead, the message should contain instructions on how to deal with the substance (TR. 347). We believe that a diluted form of warning will not suffice. We appreciate the concern of employers with the reaction of their employees. But we consider it imperative that a worker be fully informed, and that he realize the possible risks involved in his occupation. Coupled with the training requirement in the standard, we believe that the signs and labels required will adequately inform employees of the hazard. In addition, such signs will warn unauthorized personnel to keep out of regulated areas.

The proper application of most protective measures requires an amount of training and indoctrination of employees that cannot easily be conveyed on a sign or label. Also, the variety of measures that could be prescribed would result in an unwieldy or excessively detailed legend. Consequently, the required message on signs and labels will not include information on precautions, relevant symptoms, etc. The addition of suitable information by the employer would be permitted, providing it does not detract in any way from the required statement.

The requirement in the proposal for labeling containers of vinyl chloride has been amended by deleting the reference to the possible hazard of violent polymerization. Very little information was developed on this hazard during the standard-setting procedure. It does appear that this hazard is essentially under control and that the fire and carcinogenic hazards at present are the most significant. Since labeling or placarding that is in compliance with the U. S. Department of Transportation regulations (49 CFR Part 173, Subpart H) already warns of the fire hazard,

only a statement concerning the carcinogenic hazard need be added to the Department of Transportation labels.

(11) *Medical surveillance.* The principal questions that have been raised regarding medical surveillance are the necessity and efficacy of requiring certain specific serum enzyme determinations (SMA-12 series) and the application of medical examination requirements to the fabrication segments of the industry where employees are exposed to lower levels of VC. The objection has also been raised that the specification of tests and procedures interferes with the application of advances in medical knowledge.

A particular difficulty in considering medical surveillance is that the most commonly discussed lesion, angiosarcoma of the liver, currently cannot be diagnosed until the victim is terminal and, usually, within months of death. Precursor physiologic alterations, which might be reversible have not yet been directly associated with the lesion. Consequently, there are no specific diagnostic tests which can be prescribed which will determine presence or absence of this tumor at an early stage of development. However, most medical witnesses indicated that the medical tests proposed are currently the only ones available which are useful for medical surveillance (TR 121, Exh. 95, TR 589-591). Consequently the specific blood tests proposed have been retained as a minimum requirement to assist the examining physician in determining fitness of potential employees for assignment to workplaces involving VC exposure. In addition, alternative medical examinations may be used where the examining physician determines that they are at least as good as those specified by the standard.

The Tabershaw-Cooper study and the various animal experiments suggest that VC may produce a wide spectrum of malignant and non-malignant disorders. The general scope of the required medical examination has, therefore, been broadened to include kidneys, skin, connective tissue, spleen, and pulmonary system, as well as the liver. No

additional specific procedures or tests are required, but recommendations have been included in the Appendix to assist the examining physician. Because of the nonspecific nature of the required medical tests, it is not appropriate to prescribe timing, or type of followup tests, or to mandate withdrawal from exposure based solely on results of the tests. Instead, the employer is required to obtain a statement from the examining physician of the employee's suitability for continued exposure, when the examining physician has completed such tests as he considers appropriate. The employer is required to withdraw an employee only when this statement indicates that the employee may be at added risk from continued VC exposure.

As with monitoring, there appears to be no basis for complete exemption of the fabrication industry from the requirement for medical examination. The record does show fabricating establishments with concentrations of VC monitored considerably above the action level. In these instances, medical surveillance of affected employees will provide baseline data for future evaluation of their health, even if both monitoring and medical surveillance are discontinued because improved controls reduce concentrations below the action level. Where exposures are below the action level, the medical surveillance requirements do not generally apply.

(12) *Training.* A separate provision for employee training has been added to the final standard rather than including it within the section on emergency situations as in the proposal. The new paragraph provides for training of employees concerning the carcinogenic hazard of VC, emergency procedures, the need for monitoring and an annual review of the standard. It also provides for training of employees concerning the purpose for, proper use of, and limitations connected with respiratory protection.

(13) *Records and reports.* The provisions for recordkeeping contained in the final standard require the prepa-

ration and maintenance of essentially the same information required by the proposal. The major change from the original proposal is the requirement for maintenance of monitoring records and daily roster sheets of authorized persons for 30 years, instead of 20 years. Additionally, the employer is required to maintain medical records for the duration of an employee's employment plus 20 years, or 30 years, whichever is longer. The original proposal called for only 20 years.

This change has been implemented because the latency period for induction of angiosarcoma ranges up to 30 years from initial exposure. Therefore, as a minimum, medical records must be maintained for at least that long. It should be noted that spokesmen for both labor and industry recommended that this change be made.

The reporting requirements are not significantly different from those in the original proposal. However, instead of the requirement for reporting incidents which result in the release of VC into areas where employees may be exposed, the final standard clarifies our original intent by stating that only emergencies must be reported. Also the requirement for filing a detailed, written report within 15 days has been deleted. It has been concluded that submission, within 24 hours, of an initial report that includes facts immediately available, would ordinarily be sufficient. However, if the OSHA Area Director requests further information relevant to the emergency, the employer will be required to furnish such information.

(14) *Deleted portions of the proposal.* The proposal contained provisions requiring that shower facilities and change rooms be provided, and that storage or consumption of food be prohibited in regulated areas. We have deleted these provisions because it is our conclusion they are no longer necessary. Showering facilities are not required because protective clothing, where required by the final standard, should protect employees from skin absorp-

tion by direct contact with VC and because there is no reliable evidence that VC vapor is absorbed through the skin. In addition, since we anticipate that most employees will not be wearing protective clothing and that employees who wear protective clothing will change such clothing infrequently, we are not requiring that change rooms be provided.

In addition, we feel that there is inadequate evidence showing that hazardous amounts of VC can be absorbed through ingestion. For this reason, the requirement prohibiting the storage or consumption of food in regulated areas has been deleted.

The proposal also contained provisions on maintenance and decontamination, transportation loading and unloading, and polymer handling operations. These requirements are not mentioned in the final standard because attention to these items is implicit in the requirement that each employer reach the permissible exposure limit or attain the lowest feasible level.

(15) *Effective date.* In order to ensure that affected employers and employees will be informed of the existence of these provisions and that employers affected are given an opportunity to familiarize themselves and their employees with the existence of the new requirements, the effective date of the amendment to § 1910.93q will be January 1, 1975. To provide continued protection for employees until that date, the provisions currently contained in § 1910.93q are hereby promulgated, pursuant to section 6(b), 6(c) and 8(c) of the Occupational Safety and Health Act, as an occupational safety and health standard effective October 4, 1974, the amendment to § 1910.93q set out below will supersede these provisions as of January 1, 1975.

Accordingly, upon consideration of the whole record of this proceeding. Part 1910 of Title 29, Code of Federal

Regulations is amended, effective January 1, 1975, by revision of § 1910.93q to read as follows:

§ 1910.93q Vinyl chloride.

(a) *Scope and application.* (1) This section includes requirements for the control of employee exposure to vinyl chloride (chloroethene), Chemical Abstracts Service Registry No. 75014.

(2) This section applies to the manufacture, reaction, packaging, repackaging, storage, handling or use of vinyl chloride or polyvinyl chloride, but does not apply to the handling or use of fabricated products made of polyvinyl chloride.

(3) This section applies to the transportation of vinyl chloride or polyvinyl chloride except to the extent that the Department of Transportation may regulate the hazards covered by this section.

(b) *Definitions.* (1) "Action level" means a concentration of vinyl chloride of 0.5 ppm averaged over an 8-hour work day.

(2) "Assistant Secretary" means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or his designee.

(3) "Authorized person" means any person specifically authorized by the employer whose duties require him to enter a regulated area or any person entering such an area as a designated representative of employees for the purpose of exercising an opportunity to observe monitoring and measuring procedures.

(4) "Director" means the Director, National Institute for Occupational Safety and Health, U.S. Department of Health, Education, and Welfare, or his designee.

(5) "Emergency" means any occurrence such as, but not limited to, equipment failure, or operation of a relief

device which is likely to, or does, result in massive release of vinyl chloride.

(6) "Fabricated product" means a product made wholly or partly from polyvinyl chloride, and which does not require further processing at temperatures, and for times, sufficient to cause mass melting of the polyvinyl chloride resulting in the release of vinyl chloride.

(7) "Hazardous operation" means any operation, procedure, or activity where a release of either vinyl chloride liquid or gas might be expected as a consequence of the operation or because of an accident in the operation, which would result in an employee exposure in excess of the permissible exposure limit.

(8) "OSHA Area Director" means the Director for the Occupational Safety and Health Administration Area Office having jurisdiction over the geographic area in which the employer's establishment is located.

(9) "Polyvinyl chloride" means polyvinyl chloride homopolymer or copolymer before such is converted to a fabricated product.

(10) "Vinyl chloride" means vinyl chloride monomer.

(c) *Permissible exposure limit.* (1) No employee may be exposed to vinyl chloride at concentrations greater than 1 ppm averaged over any 8-hour period, and

(2) No employee may be exposed to vinyl chloride at concentrations greater than 5 ppm averaged over any period not exceeding 15 minutes.

(3) No employee may be exposed to vinyl chloride by direct contact with liquid vinyl chloride.

(d) *Monitoring.* (1) A program of initial monitoring and measurement shall be undertaken in each establishment to determine if there is an employee exposed, without

regard to the use of respirators, in excess of the action level.

(2) Where a determination conducted under paragraph (d)(1) of this section shows any employee exposures, without regard to the use of respirators in excess of the action level, a program for determining exposures for each such employee shall be established. Such a program:

(i) Shall be repeated at least monthly where any employee is exposed, without regard to the use of respirators, in excess of the permissible exposure limit.

(ii) Shall be repeated not less than quarterly where any employee is exposed, without regard to the use of respirators, in excess of the action level.

(iii) May be discontinued for any employee only when at least two consecutive monitoring determinations, made not less than 5 working days apart, show exposures for that employee at or below the action level.

(3) Whenever there has been a production, process or control change which may result in an increase in the release of vinyl chloride, or the employer has any other reason to suspect that any employee may be exposed in excess of the action level, a determination of employee exposure under paragraph (d)(1) of this section shall be performed.

(4) The method of monitoring and measurement shall have an accuracy (with a confidence level of 95 percent) of not less than plus or minus 50 percent from 0.25 through 0.5 ppm, plus or minus 35 percent from over 0.5 ppm through 1.0 ppm, and plus or minus 25 percent over 1.0 ppm. (Methods meeting these accuracy requirements are available in the "NIOSH Manual of Analytical Methods").

(5) Employees or their designated representatives shall be afforded reasonable opportunity to observe the monitoring and measuring required by this paragraph.

(e) *Regulated area.* (1) A regulated area shall be established where:

(i) Vinyl chloride or polyvinyl chloride is manufactured, reacted, repackaged, stored, handled or used; and

(ii) Vinyl chloride concentrations are in excess of the permissible exposure limit.

(2) Access to regulated areas shall be limited to authorized persons. A daily roster shall be made of authorized persons who enter.

(f) *Methods of compliance.* Employee exposures to vinyl chloride shall be controlled to at or below the permissible exposure limit provided in paragraph (c) of this section by engineering, work practice, and personal protective controls as follows:

(1) Feasible engineering and work practice controls shall immediately be used to reduce exposures to at or below the permissible exposure limit.

(2) Wherever feasible engineering and work practice controls which can be instituted immediately are not sufficient to reduce exposures to at or below the permissible exposure limit, they shall nonetheless be used to reduce exposures to the lowest practicable level, and shall be supplemented by respiratory protection in accordance with paragraph (g) of this section. A program shall be established and implemented to reduce exposures to at or below the permissible exposure limit, or to the greatest extent feasible, solely by means of engineering and work practice controls, as soon as feasible.

(3) Written plans for such a program shall be developed and furnished upon request for examination and copying to authorized representatives of the Assistant Secretary and the Director. Such plans shall be updated at least every six months.

(g) *Respiratory protection.* Where respiratory protection is required under this section:

(1) The employer shall provide a respirator which meets the requirements of this paragraph and shall assure that the employee uses such respirator, except that until December 31, 1975, wearing of respirators shall be at the discretion of each employee for exposures not in excess of 25 ppm, measured over any 15-minute period. Until December 31, 1975, each employee who chooses not to wear an appropriate respirator shall be informed at least quarterly of the hazards of vinyl chloride and the purpose, proper use, and limitations of respiratory devices.

(2) Respirators shall be selected from among those jointly approved by the Mining Enforcement and Safety Administration, Department of the Interior, and the National Institute for Occupational Safety and Health under the provisions of 30 CFR Part 11.

(3) A respiratory protection program meeting the requirements of § 1910.134 shall be established and maintained.

(4) Selection of respirators for vinyl chloride shall be as follows:

Atmospheric concentration of vinyl chloride	*Required apparatus*
(i) Unknown, or above 3,600 ppm	Open-circuit, self-contained breathing apparatus, pressure demand type, with full facepiece.
(ii) Not over 3,600 ppm	(A) Combination type C supplied air respirator, pressure demand type, with full or half facepiece, and auxiliary self-contained air supply; or
	(B) Combination type C, supplied air respirator continuous flow type, with full or half facepiece, and auxiliary self-contained air supply.
(iii) Not over 1,000 ppm	Type C, supplied air respirator continuous flow type, with full or half facepiece, helmet or hood.
(iv) Not over 100 ppm	(A) Combination type C supplied air respirator demand type, with full facepiece, and auxiliary self-contained air supply; or

Atmospheric concentration of vinyl chloride	*Required apparatus*
	(B) Open-circuit self-contained breathing apparatus with full facepiece, in demand mode; or
	(C) Type C supplied air respirator, demand type, with full facepiece.
(v) Not over 25 ppm	(A) A powered air-purifying respirator with hood, helmet, full or half facepiece, and a canister which provides a service life of at least 4 hours for concentrations of vinyl chloride up to 25 ppm, or
	(B) Gas mask, front- or back-mounted canister which provides a service life of at least 4 hours for concentrations of vinyl chloride up to 25 ppm.
(vi) Not over 10 ppm	(A) Combination type C supplied-air respirator, demand type, with half facepiece, and auxiliary self-contained air supply; or
	(B) Type C supplied-air respirator, demand type, with half facepiece; or
	(C) Any chemical cartridge respirator with an organic vapor cartridge which provides a service life of at least 1 hour for concentrations of vinyl chloride up to 10 ppm.

(5)(i) Entry into unknown concentrations or concentrations greater than 36,000 ppm (lower explosive limit) may be made only for purposes of life rescue; and

(ii) Entry into concentrations of less than 36,000 ppm, but greater than 3,600 ppm may be made only for purposes of life rescue, firefighting, or securing equipment so as to prevent a greater hazard from release of vinyl chloride.

(6) Where air-purifying respirators are used:

(i) Air-purifying cannisters or cartridges shall be replaced prior to the expiration of their service life or the end of the shift in which they are first used, whichever occurs first, and

(ii) A continuous monitoring and alarm system shall be provided where concentrations of vinyl chloride could rea-

sonably exceed the allowable concentrations for the devices in use. Such system shall be used to alert employees when vinyl chloride concentrations exceed the allowable concentrations for the devices in use.

(7) Apparatus prescribed for higher concentrations may be used for any lower concentration.

(h) *Hazardous operations.* (1) Employees engaged in hazardous operations, including entry of vessels to clean polyvinyl chloride residue from vessel walls, shall be provided and required to wear and use;

(i) Respiratory protection in accordance with paragraphs (c) and (g) of this section; and

(ii) Protective garments to prevent skin contact with liquid vinyl chloride or with polyvinyl chloride residue from vessel walls. The protective garments shall be selected for the operation and its possible exposure conditions.

(2) Protective garments shall be provided clean and dry for each use.

(i) *Emergency situations.* A written operational plan for emergency situations shall be developed for each facility storing, handling, or otherwise using vinyl chloride as a liquid or compressed gas. Appropriate portions of the plan shall be implemented in the event of an emergency. The plan shall specifically provide that:

(1) Employees engaged in hazardous operations or correcting situations of existing hazardous releases shall be equipped as required in paragraph (h) of this section;

(2) Other employees not so equipped shall evacuate the area and not return until conditions are controlled by the methods required in paragraph (f) of this section and the emergency is abated.

(j) *Training.* Each employee engaged in vinyl chloride or polyvinyl chloride operations shall be provided training in a program relating to the hazards of vinyl chloride and precautions for its safe use.

(1) The program shall include:

(i) The nature of the health hazard from chronic exposure to vinyl chloride including specifically the carcinogenic hazard;

(ii) The specific nature of operations which could result in exposure to vinyl chloride in excess of the permissible limit and necessary protective steps;

(iii) The purpose for, proper use, and limitations of respiratory protective devices;

(iv) The fire hazard and acute toxicity of vinyl chloride, and the necessary protective steps;

(v) The purpose for and a description of the monitoring program;

(vi) The purpose for, and a description of, the medical surveillance program;

(vii) Emergency procedures;

(viii) Specific information to aid the employee in recognition of conditions which may result in the release of vinyl chloride; and

(ix) A review of this standard at the employee's first training and indoctrination program, and annually thereafter.

(2) All materials relating to the program shall be provided upon request to the Assistant Secretary and the Director.

(k) *Medical surveillance.* A program of medical surveillance shall be instituted for each employee exposed, with-

out regard to the use of respirators, to vinyl chloride in excess of the action level. The program shall provide each such employee with an opportunity for examinations and tests in accordance with this paragraph. All medical examinations and procedures shall be performed by or under the supervision of a licensed physician, and shall be provided without cost to the employee.

(1) At the time of initial assignment, or upon institution of medical surveillance;

(i) A general physical examination shall be performed, with specific attention to detecting enlargement of liver, spleen or kidneys, or dysfunction in these organs, and for abnormalities in skin, connective tissues and the pulmonary system (See Appendix A).

(ii) A medical history shall be taken, including the following topics:

(A) Alcohol intake;

(B) Past history of hepatitis;

(C) Work history and past exposure to potential hepatotoxic agents, including drugs and chemicals;

(D) Past history of blood transfusions; and

(E) Past history of hospitalizations.

(iii) A serum specimen shall be obtained and determinations made of:

(A) Total bilirubin;

(B) Alkaline phosphatase;

(C) Serum glutamic oxalacetic transaminase (SGOT);

(D) Serum glutamic pyruvic transaminase (SGPT); and

(E) Gamma glustamyl transpeptidase.

(2) Examinations provided in accordance with this paragraph shall be performed at least:

(i) Every 6 months for each employee who has been employed in vinyl chloride or polyvinyl chloride manufacturing for 10 years or longer; and

(ii) Annually for all other employees.

(3) Each employee exposed to an emergency shall be afforded appropriate medical surveillance.

(4) A statement of each employee's suitability for continued exposure to vinyl chloride including use of protective equipment and respirators, shall be obtained from the examining physician promptly after any examination. A copy of the physician's statement shall be provided each employee.

(5) If any employee's health would be materially impaired by continued exposure, such employee shall be withdrawn from possible contact with vinyl chloride.

(6) Laboratory analyses for all biological specimens included in medical examinations shall be performed in laboratories licensed under 42 CFR Part 74.

(7) If the examining physician determines that alternative medical examinations to those required by paragraph (k)(1) of this section will provide at least equal assurance of detecting medical conditions pertinent to the exposure to vinyl chloride, the employer may accept such alternative examinations as meeting the requirements of paragraph (k)(1) of this section, if the employer obtains a statement from the examining physician setting forth the alternative examinations and the rationale for substitution. This statement shall be available upon request for examination and copying to authorized representatives of the Assistant Secretary and the Director.

(l) *Signs and labels.* (1) Entrances to regulated areas shall be posted with legible signs bearing the legend:

CANCER-SUSPECT AGENT AREA
AUTHORIZED PERSONNEL ONLY

(2) Areas containing hazardous operations or where an emergency currently exists shall be posted with legible signs bearing the legend:

CANCER-SUSPECT AGENT IN THIS AREA
PROTECTIVE EQUIPMENT REQUIRED
AUTHORIZED PERSONNEL ONLY

(3) Containers of polyvinyl chloride resin waste from reactors or other waste contaminated with vinyl chloride shall be legibly labeled:

CONTAMINATED WITH
VINYL CHLORIDE
CANCER-SUSPECT AGENT

(4) Containers of polyvinyl chloride shall be legibly labeled:

POLYVINYL CHLORIDE (OR TRADE NAME)
Contains
VINYL CHLORIDE
VINYL CHLORIDE IS A CANCER-SUSPECT AGENT

(5) Containers of vinyl chloride shall be legibly labeled either:

(i)

VINYL CHLORIDE
EXTREMELY FLAMMABLE GAS UNDER PRESSURE
CANCER-SUSPECT AGENT

or (ii) In accordance with 49 CFR Part 173, Parts 170-189 with the additional legend:

CANCER-SUSPECT AGENT

applied near the label or placard.

(6) No statement shall appear on or near any required sign, label or instruction which contradicts or detracts from the effect of, any required warning, information or instruction.

(m) *Records.* (1) All records maintained in accordance with this section shall include the name and social security number of each employee where relevant.

(2) Records of required monitoring and measuring, medical records, and authorized personnel rosters, shall be made and shall be available upon request for examination and copying to authorized representatives of the Assistant Secretary and the Director.

(i) Monitoring and measuring records shall:

(A) State the date of such monitoring and measuring and the concentrations determined and identify the instruments and methods used;

(B) Include any additional information necessary to determine individual employee exposures where such exposures are determined by means other than individual monitoring of employees; and

(C) Be maintained for not less than 30 years.

(ii) Authorized personnel rosters shall be maintained for not less than 30 years.

(iii) Medical records shall be maintained for the duration of the employment of each employee plus 20 years, or 30 years, whichever is longer.

(3) In the event that the employer ceases to do business and there is no successor to receive and retain his records for the prescribed period, these records shall be transmitted by registered mail to the Director, and each employee individually notified in writing of this transfer.

(4) Employees or their designated representatives shall be provided access to examine and copy records of required monitoring and measuring.

(5) Former employees shall be provided access to examine and copy required monitoring and measuring records reflecting their own exposures.

(6) Upon written request of any employee, a copy of the medical record of that employee shall be furnished to any physician designated by the employee.

(n) *Reports.* (1) Not later than 1 month after the establishment of a regulated area, the following information shall be reported to the OSHA Area Director. Any changes to such information shall be reported within 15 days.

(i) The address and location of each establishment which has one or more regulated areas; and

(ii) The number of employees in each regulated area during normal operations, including maintenance.

(2) Emergencies, and the facts obtainable at that time, shall be reported within 24 hours to the OSHA Area Director. Upon request of the Area Director, the employer shall submit additional information in writing relevant to the nature and extent of employee exposures and measures taken to prevent future emergencies of similar nature.

(3) Within 10 working days following any monitoring and measuring which discloses that any employee has been exposed, without regard to the use of respirators, in excess of the permissible exposure limit, each such employee shall be notified in writing of the results of the exposure measurement and the steps being taken to reduce the exposure to within the permissible exposure limit.

(o) *Effective dates.* (1) Until January 1, 1975, the provisions currently set forth in § 1910.93q of this Part shall apply.

(2) Effective January 1, 1975, the provisions set forth in § 1910.93q of this Part shall apply.

Appendix A—Supplementary Medical Information

When required tests under paragraph (k)(1) of this section show abnormalities, the tests should be repeated as soon as practicable, preferably within 3 to 4 weeks. If tests remain abnormal, consideration should be given to withdrawal of the employee from contact with vinyl chloride, while a more comprehensive examination is made.

Additional tests which may be useful:

A. For kidney dysfunction: urine examination for albumin, red blood cells, and ex-foliative abnormal cells.

B. Pulmonary system: Forced vital capacity, forced expiratory volume at 1 second, and chest roentgenogram (posterior-anterior, 14 x 17 inches).

C. Additional serum tests: Lactic acid dehydrogenase, lactic acid dehydrogenase isoenzyme, protein determination, and protein electrophoresis.

D. For a more comprehensive examination on repeated abnormal serum tests: Hepatitis B antigen, and liver scanning.

(Secs. 6 and 8, 84 Stat. 1596, 1599 (29 U.S.C. 655, 657); Secretary of Labor's Order No. 12-71, 36 FR 8754)

Signed at Washington, D.C., this 1st day of October, 1974.

John Stender,
Assistant Secretary of Labor.

[FR Doc. 74-23176 Filed 10-1-74; 3:54 pm]

APPENDIX C

The relevant Sections of The Occupational Safety and Health Act, 29 U.S.C. § 651, *et seq.* provide as follows:

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§ 651. Congressional statement of findings and declaration of purpose and policy.

The Congress finds that personal injuries and illnesses arising out of work situations impose a substantial burden upon, and are a hindrance to, interstate commerce in terms of lost production, wage loss, medical expenses, and disability compensation payments.

The Congress declares it to be its purpose and policy, through the exercise of its powers to regulate commerce among the several States and with foreign nations and to provide for the general welfare, to assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources—

(1) by encouraging employers and employees in their efforts to reduce the number of occupational safety and health hazards at their places of employment, and to stimulate employers and employees to institute new and perfect existing programs for providing safe and healthful working conditions;

(2) by providing that employers and employees have separate but dependent responsibilities and rights with respect to achieving safe and healthful working conditions;

(3) by authorizing the Secretary of Labor to set mandatory occupational safety and health standards applicable to businesses affecting interstate commerce, and by creating an Occupational Safety and Health Review Commission for carrying out adjudicatory functions under this chapter;

(4) by building upon advances already made through employer and employee initiative for providing safe and healthful working conditions;

(5) by providing for research in the field of occupational safety and health, including the psychological factors involved, and by developing innovative methods, techniques, and approaches for dealing with occupational safety and health problems;

(6) by exploring ways to discover latent diseases, establishing casual connections between diseases and work in environmental conditions, and conducting other research relating to health problems, in recognition of the fact that occupational health standards present problems often different from those involved in occupational safety;

(7) by providing medical criteria which will assure insofar as practicable that no employee will suffer diminished health, functional capacity, or life expectancy as a result of his work experience;

(8) by providing for training programs to increase the number and competence of personnel engaged in the field of occupational safety and health;

(9) by providing for the development and promulgation of occupational safety and health standards;

(10) by providing an effective enforcement program which shall include a prohibition against giving advance notice of any inspection and sanctions for any individual violating this prohibition;

(11) by encouraging the States to assume the fullest responsibility for the administration and enforcement of their occupational safety and health laws by providing grants to the States to assist in identifying their needs and responsibilities in the area of occupational safety and health, to develop plans in ac-

cordance with the provisions of this chapter, to improve the administration and enforcement of State occupational safety and health laws, and to conduct experimental and demonstration projects in connection therewith;

(12) by providing for appropriate reporting procedures with respect to occupational safety and health which procedures will help achieve the objectives of this chapter and accurately describe the nature of the occupational safety and health problem;

(13) by encouraging joint labor-management efforts to reduce injuries and disease arising out of employment.

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§ 652. Definitions.

For the purposes of this chapter—

(1) The term "Secretary" means the Secretary of Labor.

(2) The term "Commission" means the Occupational Safety and Health Review Commission established under this chapter.

(3) The term "commerce" means trade, traffic, commerce, transportation, or communication among the several States, or between a State and any place outside thereof, or within the District of Columbia, or a possession of the United States (other than the Trust Territory of the Pacific Islands), or between points in the same State but through a point outside thereof.

(4) The term "person" means one or more individuals, partnerships, associations, corporations, business trusts, legal representatives, or any organized group of persons.

(5) The term "employer" means a person engaged in a business affecting commerce who has employees, but does not include the United States or any State or political subdivision of a State.

(6) The term "employee" means an employee of an employer who is employed in a business of his employer which affects commerce.

(7) The term "State" includes a State of the United States, the District of Columbia, Puerto Rico, the Virgin Islands, American Samoa, Guam, and the Trust Territory of the Pacific Islands.

(8) The term "occupational safety and health standards" means a standard which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment.

(9) The term "national consensus standard" means any occupational safety and health standard or modification thereof which (1) has been adopted and promulgated by a nationally recognized standards-producing organization under procedures whereby it can be determined by the Secretary that persons interested and affected by the scope or provisions of the standard have reached substantial agreement on its adoption, (2) was formulated in a manner which afforded an opportunity for diverse views to be considered and (3) has been designated as such a standard by the Secretary, after consultation with other appropriate Federal agencies.

(10) The term "established Federal standard" means any operative occupational safety and health standard established by any agency of the United States and presently in effect, or contained in any Act of Congress in force on December 29, 1970.

(1)) The term "Committee" means the National Advisory Committee on Occupational Safety and Health established under this chapter.

(12) The term "Director" means the Director of the National Institute for Occupational Safety and Health.

(13) The term "Institute" means the National Institute for Occupational Safety and Health established under this chapter.

(14) The term "Workmen's Compensation Commission" means the National Commission on State Workmen's Compensation Laws established under this chapter.

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§ 654. Duties of employers and employees.

(a) Each employer—

(1) shall furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees;

(2) shall comply with occupational safety and health standards promulgated under this chapter.

(b) Each employee shall comply with occupational safety and health standards and all rules, regulations, and orders issued pursuant to this chapter which are applicable to his own actions and conduct.

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§ 655. Standards.

(a) Promulgation by Secretary of national consensus standards and established Federal standards; time for promulgation; conflicting standards.

Without regard to chapter 5 of Title 5 or to the other subsections of this section, the Secretary shall, as soon as practicable during the period beginning with the effective date of this chapter and ending two years after such date, by rule promulgate as an occupational safety or health standard any national consensus standard, and any established Federal standard, unless he determines that the promulgation of such a standard would not result in improved safety or health for specifically designated employees. In the event of conflict among any such standards, the the Secretary shall promulgate the standard which assures the greatest protection of the safety or health of the affected employees.

(b) Procedure for promulgation, modification, or revocation of standards.

The Secretary may by rule promulgate, modify, or revoke any occupational safety or health standard in the following manner:

(1) Whenever the Secretary, upon the basis of information submitted to him in writing by an interested person, a representative of any organization of employers or employees, a nationally recognized standards-producing organization, the Secretary of Health, Education, and Welfare, the National Institute for Occupational Safety and Health, or a State or political subdivision, or on the basis of information developed by the Secretary or otherwise available to him, determines that a rule should be promulgated in order to serve the objectives of this chapter, the Secretary may request the recommendations of an advisory committee appointed under section 656 of this title. The Secretary shall provide such an advisory committee

with any proposals of his own or of the Secretary of Health, Education, and Welfare, together with all pertinent factual information developed by the Secretary or the Secretary of Health, Education, and Welfare, or otherwise available, including the results of research, demonstration, and experiments. An advisory committee shall submit to the Secretary its recommendations regarding the rule to be promulgated within ninety days from the date of its appointment or within such longer or shorter period as may be prescribed by the Secretary, but in no event for a period which is longer than two hundred and seventy days.

(2) The Secretary shall publish a proposed rule promulgating, modifying, or revoking an occupational safety or health standard in the Federal Register and shall afford interested persons a period of thirty days after publication to submit written data or comments. Where an advisory committee is appointed and the Secretary determines that a rule should be issued, he shall publish the proposed rule within sixty days after the submission of the advisory committee's recommendations or the expiration of the period prescribed by the Secretary for such submission.

(3) On or before the last day of the period provided for the submission of written data or comments under paragraph (2), any interested person may file with the Secretary written objections to the proposed rule, stating the grounds therefore and requesting a public hearing on such objections. Within thirty days after the last day for filing such objections, the Secretary shall publish in the Federal Register a notice specifying the occupational safety or health standard to which objections have been filed and a hearing requested, and specifying a time and place for such hearing.

(4) Within sixty days after the expiration of the period provided for the submission of written data or comments under paragraph (2), or within sixty days after the completion of any hearing held under paragraph (3), the Sec-

retary shall issue a rule promulgating, modifying, or revoking an occupational safety or health standard or make a determination that a rule should not be issued. Such a rule may contain a provision delaying its effective date for such period (not in excess of ninety days) as the Secretary determines may be necessary to insure that affected employers and employees will be informed of the existence of the standard and of its terms and that employers affected are given an opportunity to familiarize themselves and their employees with the existence of the requirements of the standard.

(5) The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired.

(6)(A) Any employer may apply to the Secretary for a temporary order granting a variance from a standard or any provision thereof promulgated under this section. Such temporary order shall be granted only if the employer files an application which meets the requirements of clause (B) and establishes that (i) he is unable to comply with a standard by its effective date because of unavailability of professional or technical personnel or of materials and

equipment needed to come into compliance with the standard or because necessary construction or alteration of facilities cannot be completed by the effective date, (ii) he is taking all available steps to safeguard his employees against the hazards covered by the standard, and (iii) he has an effective program for coming into compliance with the standard as quickly as practicable. Any temporary order issued under this paragraph shall prescribe the practices, means, methods, operations, and processes which the employer must adopt and use while the order is in effect and state in detail his program for coming into compliance with the standard. Such a temporary order may be granted only after notice to employees and an opportunity for a hearing: *Provided*, That the Secretary may issue one interim order to be effective until a decision is made on the basis of the hearing. No temporary order may be in effect for longer than the period needed by the employer to achieve compliance with the standard or one year, whichever is shorter, except that such an order may be renewed not more than twice (I) so long as the requirements of this paragraph are met and (II) if an application for renewal is filed at least 90 days prior to the expiration date of the order. No interim renewal of any order may remain in effect for longer than 180 days.

(B) An application for a temporary order under this paragraph (6) shall contain:

(i) a specification of the standard or portion thereof from which the employer seeks a variance,

(ii) a representation by the employer, supported by representations from qualified persons having firsthand knowledge of the facts represented, that he is unable to comply with the standard or portion thereof and a detailed statement of the reasons therefor,

(iii) a statement of the steps he has taken and will take (with specific dates) to protect employees against the hazard covered by the standard.

(iv) a statement of when he expects to be able to comply with the standard and what steps he has taken and what steps he will take (with dates specified) to come into compliance with the standard, and

(v) a certification that he has informed his employees of the application by giving a copy thereof to their authorized representative, posting a statement giving a summary of the application and specifying where a copy may be examined at the place or places where notices to employees are normally posted, and by other appropriate means.

A description of how employees have been informed shall be contained in the certification. The information to employees shall also inform them of their right to petition the Secretary for a hearing.

(C) The Secretary is authorized to grant a variance from any standard or portion thereof whenever he determines, or the Secretary of Health, Education, and Welfare certifies, that such variance is necessary to permit an employer to participate in any experiment approved by him or the Secretary of Health, Education, and Welfare designed to demonstrate or validate new and improved techniques to safeguard the health and safety of workers.

(7) Any standard promulgated under this subsection shall prescribe the use of labels or other appropriate forms of warning as are necessary to insure that employees are apprised of all hazards to which they are exposed, relevant symptoms and appropriate emergency treatment, and proper conditions and precautions of safe use or exposure. Where appropriate, such standard shall also prescribe suitable protective equipment and control or technological procedures to be used in connection with such hazards and shall provide for monitoring or measuring employee exposure at such locations and intervals, and in such manner as may be necessary for the protection of employees. In addi-

tion, where appropriate, any such standard shall prescribe the type and frequency of medical examinations or other tests which shall be made available, by the employer or at his cost, to employees exposed to such hazards in order to most effectively determine whether the health of such employees is adversely affected by such exposure. In the event such medical examination are in the nature of research, as determined by the Secretary of Health, Education, and Welfare, such examinations may be furnished at the expense of the Secretary of Health, Education, and Welfare. The results of such examinations or tests shall be furnished only to the Secretary or the Secretary of Health, Education, and Welfare, and, at the request of the employee, to his physician. The Secretary, in consultation with the Secretary of Health, Education, and Welfare, may by rule promulgated pursuant to section 553 of Title 5, make appropriate modifications in the foregoing requirements relating to the use of labels or other forms of warning, monitoring or measuring, and medical examinations, as may be warranted by experience, information, or medical or technological developments acquired subsequent to the promulgation of the relevant standard.

(8) Whenever a rule promulgated by the Secretary differs substantially from an existing national consensus standard, the Secretary shall, at the same time, publish in the Federal Register a statement of the reasons why the rule as adopted will better effectuate the purposes of this chapter than the national consensus standard.

(c) Emergency temporary standards.

(1) The Secretary shall provide, without regard to the requirements of chapter 5 of Title 5, for an emergency temporary standard to take immediate effect upon publication in the Federal Register if he determines (A) that employees are exposed to grave danger from exposure to

substances or agents determined to be toxic or physically harmful or from new hazards, and (B) that such emergency standard is necessary to protect employees from such danger.

(2) Such standard shall be effective until superseded by a standard promulgated in accordance with the procedures prescribed in paragraph (3) of this subsection.

(4) Upon publication of such standard in the Federal Register the Secretary shall commence a proceeding in accordance with subsection (b) of this section, and the standard as published shall also serve as a proposed rule for the proceeding. The Secretary shall promulgate a standard under this paragraph no later than six months after publication of the emergency standard as provided in paragraph (2) of this subsection.

(d) Variances from standards; procedure.

Any affected employer may apply to the Secretary for a rule or order for a variance from a standard promulgated under this section. Affected employees shall be given notice of each such application and an opportunity to participate in a hearing. The Secretary shall issue such rule or order if he determines on the record, after opportunity for an inspection where appropriate and a hearing, that the proponent of the variance has demonstrated by a preponderance of the evidence that the conditions, practices, means, methods, operations, or processes used or proposed to be used by an employer will provide employment and places of employment to his employees which are as safe and healthful as those which would prevail if he complied with the standard. The rule or order so issued shall prescribe the conditions the employer must maintain, and the practices, means, methods, operations, and processes which he must adopt and utilize to the extent they differ from the standard in question. Such a rule or order may be modified or revoked upon application by an employer, employees, or

by the Secretary on his own motion, in the manner prescribed for its issuance under this subsection at any time after six months from its issuance.

(e) Statement of reasons for Secretary's determinations; publication in Federal Register.

Whenever the Secretary promulgates any standard, makes any rule, order, or decision, grants any exemption or extension of time, or compromises, mitigates, or settles any penalty assessed under this chapter, he shall include a statement of the reasons for such action, which shall be published in the Federal Register.

(f) Judicial review.

Any person who may be adversely affected by a standard issued under this section may at any time prior to the sixtieth day after such standard is promulgated file a petition challenging the validity of such standard with the United States court of appeals for the circuit wherein such person resides or has his principal place of business, for a judicial review of such standard. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary. The filing of such petition shall not, unless otherwise ordered by the court, operate as a stay of the standard. The determinations of the Secretary shall be conclusive if supported by substantial evidence in the record considered as a whole.

(g) Priority for establishment of standards.

In determining the priority for establishing standards under this section, the Secretary shall give due regard to the urgency of the need for mandatory safety and health standards for particular industries, trades, crafts, occupations, businesses, workplaces or work environments. The Secretary shall also give due regard to the recommenda-

tions of the Secretary of Health, Education, and Welfare regarding the need for mandatory standards in determining the priority for establishing such standards.

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§ 657. Inspections, investigations, and recordkeeping.

(a) Authority of Secretary to enter, inspect, and investigate places of employment; time and manner.

In order to carry out the purposes of this chapter, the Secretary, upon presenting appropriate credentials to the owner, operator, or agent in charge, is authorized—

(1) to enter without delay and at reasonable times any factory, plant, establishment, construction site, or other area, workplace or environment where work is performed by an employee of an employer; and

(2) to inspect and investigate during regular working hours and at other reasonable times, and within reasonable limits and in a reasonable manner, any such place of employment and all pertinent conditions, structures, machines, apparatus, devices, equipment, and materials therein, and to question privately any such employer, owner, operator, agent, or employee.

(b) Attendance and testimony of witnesses and production of evidence; enforcement of subpoena.

In making his inspections and investigations under this chapter the Secretary may require the attendance and testimony of witnesses and the production of evidence under oath. Witnesses shall be paid the same fees and mileage that are paid witnesses in the courts of the United States. In case of a contumacy, failure, or refusal of any person to obey such an order, any district court of the United States or the United States courts of any territory or pos-

session, within the jurisdiction of which such person is found, or resides or transacts business, upon the application by the Secretary, shall have jurisdiction to issue to such person an order requiring such person to appear to produce evidence if, as, and when so ordered, and to give testimony relating to the matter under investigation or in question, and any failure to obey such order of the court may be punished by said court as a contempt thereof.

(c) Maintenance, preservation, and availability of records; issuance of regulations; scope of records; periodic inspections by employer; posting of notices by employer; notification of employee of corrective action.

(1) Each employer shall make, keep and preserve, and make available to the Secretary or the Secretary of Health, Education, and Welfare, such records regarding his activities relating to this chapter as the Secretary, in cooperation with the Secretary of Health, Education, and Welfare, may prescribe by regulation as necessary or appropriate for the enforcement of this chapter or for developing information regarding the causes and prevention of occupational accidents and illnesses. In order to carry out the provisions of this paragraph such regulations may include provisions requiring employers to conduct periodic inspections. The Secretary shall also issue regulations requiring that employers, through posting of notices or other appropriate means, keep their employees informed of their protections and obligations under this chapter, including the provisions of applicable standards.

(2) The Secretary, in cooperation with the Secretary of Health, Education, and Welfare, shall prescribe regulations requiring employers to maintain accurate records of, and to make periodic reports on, work-related deaths, injuries and illnesses other than minor injuries requiring only first aid treatment and which do not involve medical treatment, loss of consciousness, restriction of work or motion, or transfer to another job.

(3) The Secretary, in cooperation with the Secretary of Health, Education, and Welfare, shall issue regulations requiring employers to maintain accurate records of employee exposures to potentially toxic materials or harmful physical agents which are required to be monitored or measured under section 655 of this title. Such regulations shall provide employees or their representatives with an opportunity to observe such monitoring or measuring, and to have access to the records thereof. Such regulations shall also make appropriate provision for each employee or former employee to have access to such records as will indicate his own exposure to toxic materials or harmful physical agents. Each employer shall promptly notify any employee who has been or is being exposed to toxic materials or harmful physical agents in concentrations or at levels which exceed those prescribed by an applicable occupational safety and health standard promulgated under section 655 of this title, and shall inform any employee who is being thus exposed of the corrective action being taken.

(d) Obtaining of information.

Any information obtained by the Secretary, the Secretary of Health, Education, and Welfare, or a State agency under this chapter shall be obtained with a minimum burden upon employers, especially those operating small businesses. Unnecessary duplication of efforts in obtaining information shall be reduced to the maximum extent feasible.

(e) Employer and authorized employee representatives to accompany Secretary or his authorized representative on inspection of workplace; consultation with employees where no authorized employee representative is present.

Subject to regulations issued by the Secretary, a representative of the employer and a representative authorized by his employees shall be given an opportunity to

accompany the Secretary or his authorized representative during the physical inspection of any workplace under subsection (a) of this section for the purpose of aiding such inspection. Where there is no authorized employee representative, the Secretary or his authorized representative shall consult with a reasonable number of employees concerning matters of health and safety in the workplace.

(f) Request for inspection by employees or representative of employees; grounds; procedure; determination of request; notification of Secretary or representative prior to or during any inspection of violation; procedure for review of refusal by representative of Secretary to issue a citation for alleged violations.

(1) Any employees or representative of employees who believe that a violation of a safety or health standard exists that threatens physical harm, or that an imminent danger exists, may request an inspection by giving notice to the Secretary or his authorized representative of such violation or danger. Any such notice shall be reduced to writing, shall set forth with reasonable particularity the grounds for the notice, and shall be signed by the employees or representative of employees, and a copy shall be provided the employer or his agent no later than at the time of inspection, except that, upon the request of the person giving such notice, his name and the names of individual employees referred to therein shall not appear in such copy or on any record published, released, or made available pursuant to subsection (g) of this section. If upon receipt of such notification the Secretary determines there are reasonable grounds to believe that such violation or danger exists, he shall make a special inspection in accordance with the provisions of this section as soon as practicable, to determine if such violation or danger exists. If the Secretary determines there are no reasonable grounds to believe that a violation or danger exists he shall notify the employees or representative of the employees in writing of such determination.

(2) Prior to or during any inspection of a workplace, any employees or representative of employees employed in such workplace may notify the Secretary or any representative of the Secretary responsible for conducting the inspection, in writing, of any violation of this chapter which they have reason to believe exists in such workplace. The Secretary shall, by regulations, establish procedures for informal review of any refusal by a representative of the Secretary to issue a citation with respect to any such alleged violation and shall furnish the employees or representative of employees requesting such review a written statement of the reasons for the Secretary's final disposition of the case.

(g) Compilation analysis, and publication of reports and information; rules and regulations.

(1) The Secretary and Secretary of Health, Education, and Welfare are authorized to compile, analyze, and publish, either in summary or detailed form, all reports or information obtained under this section.

(2) The Secretary and the Secretary of Health, Education, and Welfare shall each prescribe such rules and regulations as he may deem necessary to carry out their responsibilities under this chapter, including rules and regulations dealing with the inspection of an employer's establishment.

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§ 658. Citations.

(a) Authority to issue; grounds; contents; notice in lieu of citation for de minimis violations.

If, upon inspection or investigation, the Secretary or his authorized representative believes that an employer has violated a requirement of section 654 of this title, of any standard, rule or order promulgated pursuant to section 655 of this title, or of any regulations prescribed pursuant to this chapter, he shall with reasonable promptness

issue a citation to the employer. Each citation shall be in writing and shall describe with particularity the nature of the violation, including a reference to the provision of the chapter, standard, rule, regulation, or order alleged to have been violated. In addition, the citation shall fix a reasonable time for the abatement of the violation. The Secretary may prescribe procedures for the issuance of a notice in lieu of a citation with respect to de minimis violations which have no direct or immediate relationship to safety or health.

(b) Posting.

Each citation issued under this section, or a copy or copies thereof, shall be prominently posted, as prescribed in regulations issued by the Secretary, at or near each place a violation referred to in the citation occurred.

(c) Time for issuance.

No citation may be issued under this section after the expiration of six months following the occurrence of any violation.

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§ 659. Enforcement procedures.

(a) Notification of employer of proposed assessment of penalty subsequent to issuance of citation; time for notification of Secretary by employer of contest by employer of citation or proposed assessment; citation and proposed assessment as final order upon failure of employer to notify of contest and failure of employees to file notice.

If, after an inspection or investigation, the Secretary issues a citation under section 658(a) of this title, he shall, within a reasonable time after the termination of such inspection or investigation, notify the employer by certified mail of the penalty, if any, proposed to be assessed under

section 666 of this title and that the employer has fifteen working days within which to notify the Secretary that he wishes to contest the citation or proposed assessment of penalty. If, within fifteen working days from the receipt of the notice issued by the Secretary the employer fails to notify the Secretary that he intends to contest the citation or proposed assessment of penalty, and no notice is filed by any employee or representative of employees under subsection (c) of this section within such time, the citation and the assessment, as proposed, shall be deemed a final order of the Commission and not subject to review by any court or agency.

(b) Notification of employer of failure to correct in allotted time period violation for which citation was issued and proposed assessment of penalty for failure to correct; time for notification of Secretary by employer of contest by employer of notification of failure to correct or proposed assessment; notification or proposed assessment as final order upon failure of employer to notify of contest.

If the Secretary has reason to believe that an employer has failed to correct a violation for which a citation has been issued within the period permitted for its correction (which period shall not begin to run until the entry of a final order by the Commission in the case of any review proceedings under this section initiated by the employer in good faith and not solely for delay or avoidance of penalties), the Secretary shall notify the employer by certified mail of such failure and of the penalty proposed to be assessed under section 666 of this title by reason of such failure, and that the employer has fifteen working days within which to notify the Secretary that he wishes to contest the Secretary's notification or the proposed assessment of penalty. If, within fifteen working days from the receipt of notification issued by the Secretary, the employer fails to notify the Secretary that he intends to contest the

notification or proposed assessment of penalty, the notification and assessment, as proposed, shall be deemed a final order of the Commission and not subject to review by any court or agency.

(c) Advisement of Commission by Secretary of notification of contest by employer of citation or of filing of notice by any employee or representative of employees; hearing by Commission; orders of Commission and Secretary; rules of procedure.

If an employer notifies the Secretary that he intends to contest a citation issued under section 658(a) of this title or notification issued under subsection (a) or (b) of this section, or if, within fifteen working days of the issuance of a citation under section 658(a) of this title, any employee or representative of employees files a notice with the Secretary alleging that the period of time fixed in the citation for the abatement of the violation is unreasonable, the Secretary shall immediately advise the Commission of such notification, and the Commission shall afford an opportunity for a hearing (in accordance with section 554 of Title 5 but without regard to subsection (a)(3) of such section). The Commission shall thereafter issue an order, based on findings of fact, affirming, modifying, or vacating the Secretary's citation or proposed penalty, or directing other appropriate relief, and such order shall become final thirty days after its issuance. Upon a showing by an employer of a good faith effort to comply with the abatement requirements of a citation, and that abatement has not been completed because of factors beyond his reasonable control, the Secretary, after an opportunity for a hearing as provided in this subsection, shall issue an order affirming or modifying the abatement requirements in such citation. The rules of procedure prescribed by the Commission shall provide affected employees or representatives of affected employees an opportunity to participate as parties to hearings under this subsection.

§ 660. Judicial review.

(a) Filing of petition by persons adversely affected or aggrieved; order subject to review; jurisdiction; venue; procedure; conclusiveness of record and findings of Commission; appropriate relief; finality of judgment.

Any person adversely affected or aggrieved by an order of the Commission issued under subsection (c) of section 659 of this title may obtain a review of such order in any United States court of appeals for the circuit in which the violation is alleged to have occurred or where the employer has its principal office, or in the Court of Appeals for the District of Columbia Circuit, by filing in such court within sixty days following the issuance of such order a written petition praying that the order be modified or set aside. A copy of such petition shall be forthwith transmitted by the clerk of the court to the Commission and to the other parties, and thereupon the Commission shall file in the court the record in the proceeding as provided in section 2112 of Title 28. Upon such filing, the court shall have jurisdiction of the proceeding and of the question determined therein, and shall have power to grant such temporary relief or restraining order as it deems just and proper, and to make and enter upon the pleadings, testimony, and proceedings set forth in such record a decree affirming, modifying, or setting aside in whole or in part, the order of the Commission and enforcing the same to the extend that such order is affirmed or modified. The com-

mencement of proceedings under this subsection shall not, unless ordered by the court, operate as a stay of the order of the Commission. No objection that has not been urged before the Commission shall be considered by the court, unless the failure or neglect to urge such objection shall be excused because of extraordinary circumstances. The findings of the Commission with respect to questions of fact, if supported by substantial evidence on the record considered as a whole, shall be conclusive. If any party shall apply to the court for leave to adduce additional evidence and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the hearing before the Commission, the court may order such additional evidence to be taken before the Commission and to be made a part of the record. The Commission may modify its findings as to the facts, or make new findings, by reason of additional evidence so taken and filed, and it shall file such modified or new findings, which findings with respect to questions of fact, if supported by substantial evidence on the record considered as a whole, shall be conclusive, and its recommendations, if any, for the modification or setting aside of its original order. Upon the filing of the record with it, the jurisdiction of the court shall be exclusive and its judgment and decree shall be final, except that the same shall be subject to review by the Supreme Court of the United States, as provided in section 1254 of Title 28. Petitions filed under this subsection shall be heard expeditiously.

(b) Filing of petition by Secretary; orders subject to review; jurisdiction; venue; procedure; conclusiveness of record and findings of Commission; enforcement of orders; contempt proceedings.

The Secretary may also obtain review or enforcement of any final order of the Commission by filing a petition for such relief in the United States court of appeals for the circuit in which the alleged violation occurred or in which the employer has its principal office, and the provisions of subsection (a) of this section shall govern such proceedings to the extent applicable. If no petition for review, as provided in subsection (a) of this section, is filed within sixty days after service of the Commission's order, the Commission's findings of fact and order shall be conclusive in connection with any petition for enforcement which is filed by the Secretary after the expiration of such sixty-day period. In any such case, as well as in the case of a noncontested citation or notification by the Secretary which has become a final order of the Commission under subsection (a) or (b) of section 659 of this title, the clerk of the court, unless otherwise ordered by the court, shall forthwith enter a decree enforcing the order and shall transmit a copy of such decree to the Secretary and the employer named in the petition. In any contempt proceeding brought to enforce a decree of a court of appeals entered pursuant to this subsection or subsection (a) of this section, the court of appeals may assess the penalties provided in section 666 of this section, in addition to invoking any other available remedies.

(c) Discharge or discrimination against employee for exercise of rights under this chapter; prohibition; procedure for relief.

(1) No person shall discharge or in any manner discriminate against any employee because such employee has filed any complaint or instituted or caused to be instituted

any proceeding under or related to this chapter or has testified or is about to testify in any such proceeding or because of the exercise by such employee on behalf of himself or others of any right afforded by this chapter.

(2) Any employee who believes that he has been discharged or otherwise discriminated against by any person in violation of this subsection may, within thirty days after such violation occurs, file a complaint with the Secretary alleging such discrimination. Upon receipt of such complaint, the Secretary shall cause such investigation to be made as he deems appropriate. If upon such investigation, the Secretary determines that the provisions of this subsection have been violated, he shall bring an action in any appropriate United States district court against such person. In any such action the United States district courts shall have jurisdiction, for cause shown to restrain violations of paragraph (1) of this subsection and order all appropriate relief including rehiring or reinstatement of the employee to his former position with back pay.

(3) Within 90 days of the receipt of a complaint filed under this subsection the Secretary shall notify the complainant of his determination under paragraph (2) of this subsection.

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§ 666. Civil and criminal penalties.

(a) Any employer who willfully or repeatedly violates the requirements of section 654 of this title, any standard, rule, or order promulgated pursuant to section 655 of this title, or regulations prescribed pursuant to this chapter, may be assessed a civil penalty of not more than $10,000 for each violation.

(b) Any employer who has received a citation for a serious violation of the requirements of section 654 of this title, of any standard, rule, or order promulgated pursuant to section 655 of this title, or of any regulations prescribed

pursuant to this chapter, shall be assessed a civil penalty of up to $1,000 for each such violation.

(c) Any employer who has received a citation for a violation of the requirements of section 654 of this title, of any standard, rule, or order promulgated pursuant to section 655 of this title, or of regulations prescribed pursuant to this chapter, and such violation is specifically determined not to be of a serious nature, may be assessed a civil penalty of up to $1,000 for each such violation.

(d) Any employer who fails to correct a violation for which a citation has been issued under section 658(a) of this title within the period permitted for its correction (which period shall not begin to run until the date of the final order of the Commission in the case of any review proceeding under section 659 of this title initiated by the employer in good faith and not solely for delay or avoidance of penalties), may be assessed a civil penalty of not more than $1,000 for each day during which such failure or violation continues.

(e) Any employer who willfully violates any standard, rule, or order promulgated pursuant to section 655 of this title, or of any regulations prescribed pursuant to this chapter, and that violation caused death to any employee, shall, upon conviction, be punished by a fine of not more than $10,000 or by imprisonment for not more than six months, or by both; except that if the conviction is for a violation committed after a first conviction of such person, punishment shall be by a fine of not more than $20,000 or by imprisonment for not more than one year, or by both.

(f) Any person who gives advance notice of any inspection to be conducted under this chapter, without authority from the Secretary or his designees, shall, upon conviction, be punished by a fine of not more than $1,000 or by imprisonment for not more than six months, or by both.

(g) Whoever knowingly makes any false statement, representation, or certification in any application, record, report, plan, or other document filed or required to be maintained pursuant to this chapter shall, upon conviction, be punished by a fine of not more than $10,000, or by imprisonment for not more than six months, or by both.

(h) Any employer who violates any of the posting requirements, as prescribed under the provisions of this chapter, shall be assessed a civil penalty of up to $1,000 for each violation.

(i) The Commission shall have authority to assess all civil penalties provided in this section, giving due consideration to the appropriateness of the penalty with respect to the size of the business of the employer being charged, the gravity of the violation, the good faith of the employer, and the history of previous violations.

(j) For purposes of this section, a serious violation shall be deemed to exist in a place of employment if there is a substantial probability that death or serious physical harm could result from a condition which exists, or from one or more practices, means, methods, operations, or processes which have been adopted or are in use, in such place of employment unless the employer did not, and could not with the exercise of reasonable diligence, know of the presence of the violation.

(k) Civil penalties owed under this chapter shall be paid to the Secretary for deposit into the Treasury of the United States and shall accrue to the United States and may be recovered in a civil action in the name of the United States brought in the United States district court for the district where the violation is alleged to have occurred or where the employer has its principal office.

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§ 669. Research and related activities.

(a) Authority of Secretary of Health, Education, and Welfare to conduct research, experiments, and demonstrations, develop plans, establish criteria; promulgate regulations, authorize programs, and publish results and industrywide studies; consultations.

(1) The Secretary of Health, Education, and Welfare, after consultation with the Secretary and with other appropriate Federal departments or agencies, shall conduct (directly or by grants or contracts) research, experiments, and demonstrations relating to occupational safety and health, including studies of psychological factors involved, and relating to innovative methods, techniques, and approaches for dealing with occupational safety and health problems.

(2) The Secretary of Health, Education, and Welfare shall from time to time consult with the Secretary in order to develop specific plans for such research, demonstrations, and experiments as are necessary to produce criteria, including criteria identifying toxic substances, enabling the Secretary to meet his responsibility for the formulation of safety and health standards under this chapter; and the Secretary of Health, Education, and Welfare on the basis of such research, demonstrations, and experiments and any other information available to him, shall develop and publish at least annually such criteria as will effectuate the purposes of this chapter.

(3) The Secretary of Health, Education, and Welfare, on the basis of such research, demonstrations, and experiments, and any other information available to him, shall develop criteria dealing with toxic materials and harmful physical agents and substances which will describe exposure levels that are safe for various periods of employment, including but not limited to the exposure levels at which no employee will suffer impaired health or functional

capacities or diminished life expectancy as a result of his work experience.

(4) The Secretary of Health, Education, and Welfare shall also conduct special research, experiments, and demonstrations relating to occupational safety and health as are necessary to explore new problems, including those created by new technology in occupational safety and health, which may require ameliorative action beyond that which is otherwise provided for in the operating provisions of this chapter. The Secretary of Health, Education, and Welfare shall also conduct research into the motivational and behavioral factors relating to the field of occupational safety and health.

(5) The Secretary of Health, Education, and Welfare, in order to comply with his responsibilities under paragraph (2), and in order to develop needed information regarding potentially toxic substances or harmful physical agents, may prescribe regulations requiring employers to measure, record, and make reports on the exposure of employees to substances or physical agents which the Secretary of Health, Education, and Welfare reasonably believes may endanger the health or safety of employees. The Secretary of Health, Education, and Welfare also is authorized to establish such programs of medical examinations and tests as may be necessary for determining the incidence of occupational illnesses and the susceptibility of employees to such illnesses. Nothing in this or any other provision of this chapter shall be deemed to authorize or require medical examination, immunization, or treatment for those who object thereto on religious grounds, except where such is necessary for the protection of the health or safety of others. Upon the request of any employer who is required to measure and record exposure of employees to substances or physical agents as provided under this subsection, the Secretary of Health, Education and Welfare shall furnish full financial or other assistance to such

employer for the purpose of defraying any additional expense incurred by him in carrying out the measuring and recording as provided in this subsection.

(6) The Secretary of Health, Education, and Welfare shall publish within six months of December 29, 1970, and thereafter as needed but at least annually a list of all known toxic substances by generic family or other useful grouping, and the concentrations at which such toxicity is known to occur. He shall determine following a written request by any employer or authorized representative of employees, specifying with reasonable particularity the grounds on which the request is made, whether any substance normally found in the place of employment has potentially toxic effects in such concentrations as used or found; and shall submit such determination both to employers and affected employees as soon as possible. If the Secretary of Health, Education, and Welfare determines that any substance is potentially toxic at the concentrations in which it is used or found in a place of employment, and such substance is not covered by an occupational safety or health standard promulgated under section 655 of this title, the Secretary of Health, Education, and Welfare shall immediately submit such determination to the Secretary, together with all pertinent criteria.

(7) Within two years of December 29, 1970, and annually thereafter the Secretary of Health, Education, and Welfare shall conduct and publish industrywide studies of the effect of chronic or low-level exposure to industrial materials, processes, and stresses on the potential for illness, disease, or loss of functional capacity in aging adults.

(b) Authority of Secretary of Health, Education, and Welfare to make inspections and question employers and employees.

The Secretary of Health, Education, and Welfare is authorized to make inspections and question employers and

employees as provided in section 657 of this title in order to carry out his functions and responsibilities under this section.

(c) Contracting authority of Secretary of Labor; cooperation between Secretary of Labor and Secretary of Health, Education, and Welfare.

The Secretary is authorized to enter into contracts, agreements, or other arrangements with appropriate public agencies or private organizations for the purpose of conducting studies relating to his responsibilities under this chapter. In carrying out his responsibilities under this subsection, the Secretary shall cooperate with the Secretary of Health, Education, and Welfare in order to avoid any duplication of efforts under this section.

(d) Dissemination of information to interested parties.

Information obtained by the Secretary and the Secretary of Health, Education, and Welfare under this section shall be disseminated by the Secretary to employers and employees and organizations thereof.

(e) Delegation of functions of Secretary of Health, Education, and Welfare to Director of the National Institute for Occupational Safety and Health.

The functions of the Secretary of Health, Education, and Welfare under this chapter shall, to the extent feasible, be delegated to the Director of the National Institute for Occupational Safety and Health established by section 671 of this title.

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§ 671. National Institute for Occupational Safety and Health.

(a) Statement of purpose.

It is the purpose of this section to establish a National Institute for Occupational Safety and Health in the De-

partment of Health, Education, and Welfare in order to carry out the policy set forth in section 651 of this title and to perform the functions of the Secretary of Health, Education, and Welfare under sections 669 and 670 of this title.

(b) Establishment; Director; appointment; term.

There is hereby established in the Department of Health, Education, and Welfare a National Institute for Occupational Safety and Health. The Institute shall be headed by a Director who shall be appointed by the Secretary of Health, Education, and Welfare, and who shall serve for a term of six years unless previously removed by the Secretary of Health, Education, and Welfare.

(c) Development and establishment of standards; performance of functions of Secretary of Health, Education, and Welfare.

The Institute is authorized to—

(1) develop and establish recommended occupational safety and health standards; and

(2) perform all functions of the Secretary of Health, Education, and Welfare under sections 669 and 670 of this title.

(d) Authority of Director.

Upon his own initiative, or upon the request of the Secretary or the Secretary of Health, Education, and Welfare, the Director is authorized (1) to conduct such research and experimental programs as he determines are necessary for the development of criteria for new and improved occupational safety and health standards, and (2) after consideration of the results of such research and experimental programs make recommendations concerning new or improved occupational safety and health standards. Any oc-

cupational safety and health standard recommended pursuant to this section shall immediately be forwarded to the Secretary of Labor, and to the Secretary of Health, Education, and Welfare.

(e) Additional authority of Director.

In addition to any authority vested in the Institute by other provisions of this section, the Director, in carrying out the functions of the Institute, is authorized to—

(1) prescribe such regulations as he deems necessary governing the manner in which its functions shall be carried out;

(2) receive money and other property donated, bequeathed, or devised, without condition or restriction other than that it be used for the purposes of the Institute and to use, sell, or otherwise dispose of such property for the purpose of carrying out its functions;

(3) receive (and use, sell, or otherwise dispose of, in accordance with paragraph (2)), money and other property donated, bequeathed, or devised to the Institute with a condition or restriction, including a condition that the Institute use other funds of the Institute for the purposes of the gift;

(4) in accordance with the civil service laws, appoint and fix the compensation of such personnel as may be necessary to carry out the provisions of this section;

(5) obtain the services of experts and consultants in accordance with the provisions of section 3109 of Title 5;

(6) accept and utilize the services of voluntary and noncompensated personnel and reimburse them for travel expenses, including per diem, as authorized by section 5703 of Title 5;

(7) enter into contracts, grants, or other arrangements, or modifications thereof to carry out the pro-

visions of this section, and such contracts or modifications thereof may be entered into without performance or other bonds, and without regard to section 5 of Title 41, or any other provision of law relating to competitive bidding;

(8) make advance, progress, and other payments which the Director deems necessary under this title without regard to the provisions of section 529 of Title 31; and

(9) make other necessary expenditures.

(f) Annual reports.

The Director shall submit to the Secretary of Health, Education, and Welfare, to the President, and to the Congress an annual report of the operations of the Institute under this chapter, which shall include a detailed statement of all private and public funds received and expended by it, and such recommendations as he deems appropriate.

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§ 673. Statistics.

(a) Development and maintenance of program of collection, compilation, and analysis; employments subject to coverage; scope.

In order to further the purposes of this chapter the Secretary, in consultation with the Secretary of Health, Education, and Welfare, shall develop and maintain an effective program of collection, compilation, and analysis of occupational safety and health statistics. Such program may cover all employments whether or not subject to any other provisions of this chapter but shall not cover employments excluded by section 653 of this title. The Secretary shall compile accurate statistics on work injuries and illnesses which shall include all disabling, serious, or

significant injuries and illnesses, whether or not involving loss of time from work, other than minor injuries requiring only first aid treatment and which do not involve medical treatment, loss of consciousness, restriction of work or motion, or transfer to another job.

(b) Authority of Secretary to promote, encourage, or engage in programs, make grants, and grant or contract for research and investigations.

To carry out his duties under subsection (a) of this section, the Secretary may—

(1) promote, encourage, or directly engage in programs of studies, information and communication concerning occupational safety and health statistics;

(2) make grants to States or political subdivisions thereof in order to assist them in developing and administering programs dealing with occupational safety and health statistics; and

(3) arrange, through grants or contracts, for the conduct of such research and investigations as give promise of furthering the objectives of this section.

(c) Federal share for grants.

The Federal share for each grant under subsection (b) of this section may be up to 50 per centum of the State's total cost.

(d) Utilization by Secretary of State or local services, facilities, and employees; consent; reimbursement.

The Secretary may, with the consent of any State or political subdivision thereof, accept and use the services, facilities, and employees of the agencies of such State or political subdivision, with or without reimbursement, in order to assist him in carrying out his functions under this section.

(e) Reports by employers.

On the basis of the records made and kept pursuant to section 657(c) of this title, employers shall file such reports with the Secretary as he shall prescribe by regulation, as necessary to carry out his functions under this chapter.

(f) Supersedure of agreements between Department of Labor and States for collection of statistics.

Agreements between the Department of Labor and States pertaining to the collection of occupational safety and health statistics already in effect on the effective date of this chapter shall remain in effect until superseded by grants or contracts made under this chapter.